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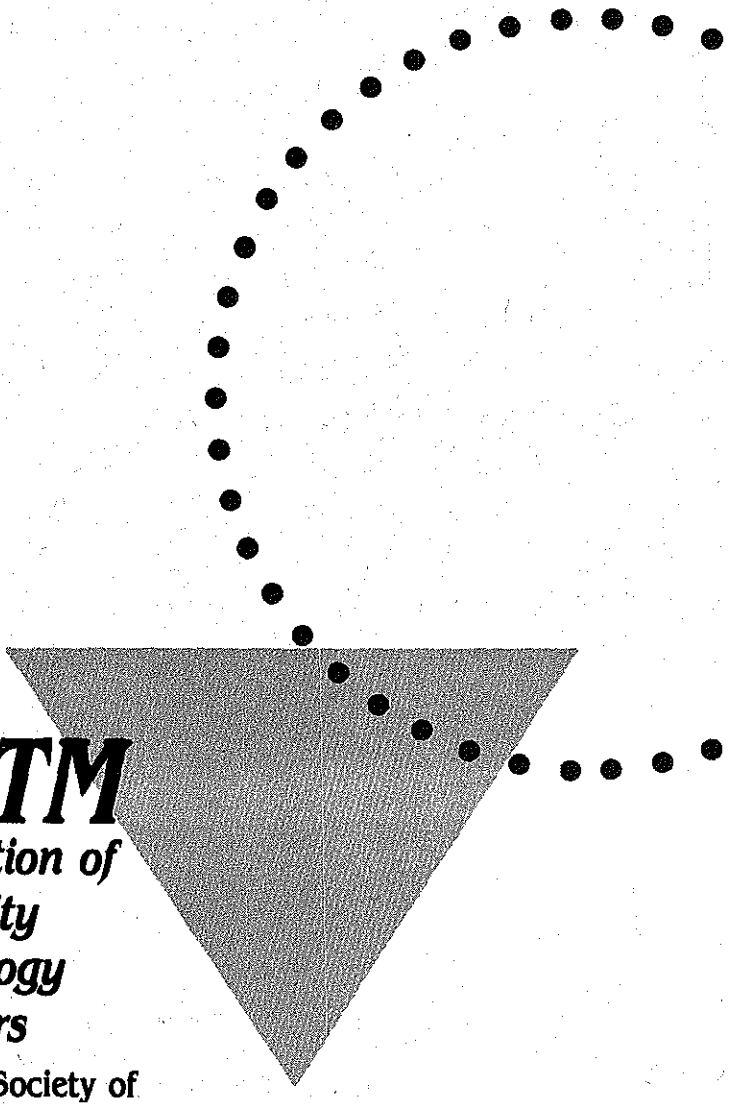

AUTM

Association of University Technology Managers

(formerly Society of

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1991

Journal of the Association of University Technology Managers

AUTM
Association of University Technology Managers
(formerly Society of University Patent Administrators)

JOURNAL
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ASSOCIATION OF UNIVERSITY
TECHNOLOGY MANAGERS

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Ms. Penny Dalziel
Association of University Technology Managers
71 East Avenue, Suite S
Norwalk, CT 06851-4903
Phone: 203\852-7168
FAX: 203\838-5714

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The Journal of the Association of University Technology Managers

Volume 3 1991

Editor's Preface

Volume III of the *AUTM Journal* commemorates the passage of P.L. 96-517, the Patent and Trademark Law Amendments Act, a little more than ten years ago. The first two articles offer historical perspectives on the field of technology transfer and examine the rationale for universities to engage in the field, while the others focus on new issues that have presented themselves as a result of the Dole-Bayh Act.

In his article entitled "Public Law 96-517 and Risk Capital: The Laboratory-Market Connection", Roger Ditzel analyzes the impact of the law through a variety of factors. He addresses the issues raised by critics of the idea of allowing patent rights arising from government-supported research to rest with universities, and makes the strong case in favor of universities engaging in technology transfer. Ditzel presents statistics from the University of California system, whose nine campuses conduct ten percent of all university research in the United States, looking at patenting activity, licensing income, and new products arising from such patents.

Charles Cary's article, "A Decade of Growth", illustrates trends in the academic technology transfer process over the last decade, and provides us with a view into his personal crystal ball as he makes predictions as to the future of technology transfer at American universities.

Jerald Rosenblum and Kathy Fields turn to a relatively new problem facing universities since the advent of the Dole-Bayh Act, namely, that of product liability. They present a discussion of the topic, including its chilling effect on university licensing activity, and propose a legislative solution to this difficult doctrine. This paper was adapted from a workshop given by the authors at the annual meeting of AUTM held in San Francisco, February 25 - 26, 1991.

The two final papers focus on the recent practice of patenting and licensing biological materials. In his article on the treatment of tangible personal property in the licensing of patented biotechnology, Walter Kirn describes the use of the legal form known as "Bailment" to protect all the parties involved in such transfers.

Continuing the discussion of patented biological materials, Joan McCormack's paper, developed from her workshop at the 1991 AUTM annual meeting, presents a history of the patenting of transgenic animals, and provides a forum on the various issues surrounding this controversial practice.

The Editor is grateful for the assistance of Ms. Chizuko Walter and the support for this journal from the Office of Research and Project Administration at Princeton University.

The *AUTM Journal* welcomes original papers on topics of interest to professional technology managers. Authors contemplating a potential article are encouraged to contact a member of the advisory review board or the editor.

Jean A. Mahoney
Editor
September 1991

Public Law 96-517 and Risk Capital: The Laboratory-Market Connection

Roger G. Ditzel*

ABSTRACT

The wisdom of leaving patent rights arising under government-funded research with the university where the invention arose, heavily debated in the late 1970's, can now be judged in the light of history. The debated issues of the need to dedicate these inventions to the public, of potential altering of research programs, of withholding publication, and of inappropriate "chasing of money" by faculty and university administrators are examined in light of ten years of experience under Public Law 96-517. Data show the importance of university research to new industrial products and changes in the use of the patent system by universities. Bottom-line results of the University of California system are presented as background material for furthering dialogue and understanding of this subject so vital to the availability of new and important products to the citizens of the United States.

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*Roger G. Ditzel is Director, Technology Management, Office of the President, University of California, Alameda, CA 94501. *This paper was originally presented at the meeting, Licensing of Biological Inventions, at the University of Minnesota, January 28, 1991.*

Two hundred years ago the United States patent system was born, implementing an important government policy founded in the Constitution. By encouraging innovation through the prospect of reward to those willing to take the risk of trying, that system well served the country, the inventors, and the population. Unfortunately, the system developed a major flaw as the funding source for university basic research shifted to the federal government three decades ago.

The flaw arose when federal agency administrative decisions effectively denied the advantages of the United States patent system to university-employed inventors whose research was funded by the federal government. There were 26 different agency policies covering the subject, varying from assignment to the sponsoring agency, to restraints on title, to total neglect.

The flaw created chaos and was an administrative nightmare for inventors and their institutions. As a result, many institutions and their employees simply ignored the identification, reporting, and licensing of inventions. Fortunately, not everyone ran from the vision that there had to be a better way.

By the mid 1960's into the early 1970's, the Department of Health, Education and Welfare (and later the National Science Foundation) led the way in correcting this inequity with a move sharply criticized by many at the time. Those two agencies had the boldness to let institutions of higher education retain title to inventions made by their employees using agency funding.

The mechanism used to implement that move was an "Institutional Patent Agreement," or IPA. Each IPA provided certain protection against abuse, including a royalty-free license to the government, an assurance of diligence in licensing, and an obligation on the institution to pay for patent costs out of its own funds.

HEW was truly an entrepreneurial and courageous leader in pioneering a change in government policy that brought unprecedented growth in the number of products based on university inventions reaching the market. The agency (now known as HHS) had numerous and vocal critics. Arguments

against allowing any university to retain patent rights arising under government sponsored research included:

- what the public paid for should be owned by the public
- no university would be able to resist making money by creating situations that would result in conflicts of interest
- faculty would change the direction of research so they could get rich by working on inventions that could be licensed for a big financial payoff to them through inventor's shares of income
- industry could not be trusted to deal fairly with universities and would use the process to keep new products off the market
- publication of the results of federally funded research would be delayed or omitted in favor of the patenting process.

The arguments were made for and against the IPA concept in numerous Congressional hearings over several years, as champions of the cause convinced some in Congress that the idea had some very promising possibilities with respect to enhancing the payoff from federally funded university research.

Ten years ago, on December 12, 1980, the flaw in the system was corrected. The potential of the university invention was unshackled by the passage of Public Law 96-517, also known as the Dole-Bayh Act. Modeled on the HEW Institutional Patent Agreements, this singular act created an effective means for the university to couple its creative genius with the risk capital essential to the development and marketing of a myriad of new products. The timing was especially important to the biotechnology industry that was just emerging. It was more than important -- it was crucial.

Now, ten years later, we can see that law has had the desired effect of luring risk capital and connecting it with the university laboratory's inchoate inventions.* It has not had the dire effects predicted by its early critics: most major universities have policies in place to prevent the feared abusive conflicts.

Public Law 96-517 has been and is effective because it allows the retention of patent rights by a university to inventions arising under federal funding to that institution. Those patent rights can be bought, sold, or leased -- that is, licensed to the private sector for development and marketing of new products. Because so much university research was supported by federal funding, the change was just what industry was looking for: a reduction in the financial risk in the very risky business of developing new products. The law went one step further by extending the same rights of retaining title to small businesses. This allowed these businesses to retain title to improvements on inventions that they first licensed from a university, even when the small business used government money to do further research on the university invention.

The result was predictable. Risk capital flowed to connect the university laboratory to the market. To be sure, other factors were also important, including the favorable tax treatment of research costs. The condition essential to the success of the connection, however, was the right to exclude others offered by the patent system, and the risk reduction it provided to investors.

During the past decade, technology transfer increasingly has become recognized as important to the economy. The term has come to be a symbol -- a rallying cry -- for the effort to bring back national technological and manufacturing competitiveness through a variety of actions, including decreasing the constraints on interaction among the industrial, educational, and governmental sectors.

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*The term "risk capital" is used in the broad sense, and includes not only start-up venture capital formations, but also the traditional large and small manufacturing company's investments in research conducted by others.

While the term "technology transfer" has become very popular in the last few years, the meaning has varied greatly with the user of the term. It has been applied to a wide variety of activities involving participants from industry and universities, even to continuing education courses and traditional scholarly publications. We use a more traditional context defined as "that process in which intellectual property or related rights are transferred by contract from a university to an industrial company, which then makes or sells the products or furnishes services based on the licensed rights." Perhaps the term technology licensing is more appropriate to my discussion. While many highly productive activities described by others as technology transfer are important to increased education, skill transfer, and the availability of information important to commercialization, they are beyond the scope of this discussion.

For an understanding of the impact I have asserted for Public Law 96-517, we may properly ask:

- Is industry dependent on academic research for new products?
- Has the use of the patent system by universities changed over the last decade?
- What universities are leaders in the field, and what type of inventions do they emphasize?
- What is the bottom line after ten years?

Data to give at least partial answers to some of these questions are available from the National Science Foundation publication *Science and Engineering Indicators-1989*. I will supplement those data with statistics from the University of California system, whose nine campuses conduct ten percent of all United States university research.

I. Is industry dependent on academic research for new products?

The answer varies with the sector, but for the seven sectors listed in Table 1, the answer is "yes" for pharmaceuticals, information processing and even metals. Licensing experience also indicates that medical diagnostics and imaging are as heavily dependent on academic research as are drugs.

Table 1: Percentage of new Products and Processes Based on Recent Academic Research for Seven U.S. Industries — 1975-85

Industry	Percentage whose development depended on recent academic research*	
	Products	Processes
Information processing	28	27
Electrical	9	7
Chemical	8	6
Instruments	21	3
Drugs	44	37
Metals	22	21
Oil	2	2

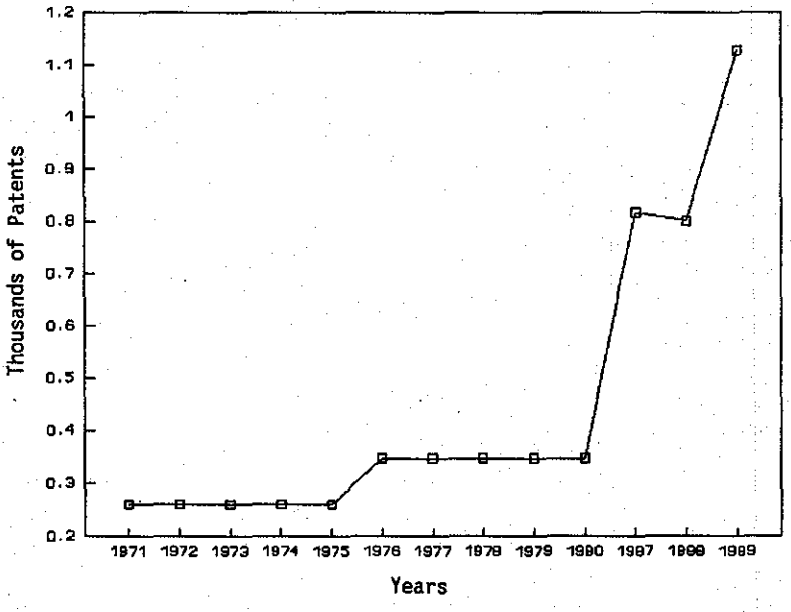
*Percentage that either could not have been developed (without substantial delay) in the absence of recent academic research or that were developed with very substantial aid from recent academic research.

Source: Mansfield (forthcoming, 1990). *Science & Engineering Indicators — 1989.*

II. Has the use of the patent system by universities changed over the last decade? What evidence is there that the availability of the patent system to university inventors as a result of PL 96-517 made any difference?

Referring to Figure 1, the number of patents issued to United States universities increased from an average of about 300 per year in the 1970s to over 1,100 in 1989. There was an increase in the last half of the 70s, probably because of increased activity at a few institutions. The rapid increase in patents issued to universities took place after the passage of PL 96-517. Some of the increase (but certainly not the majority) can be attributed to the emergence of biotechnology from university laboratories. Other data show a similar and dramatic increase in the number of members of the Association of University Technology Managers between the early 1980s and today.

Figure 1: United States Academic Patenting Activity 1971-1989



The number of patents issued is a direct measure of the confidence among universities that some meaningful percentage of them could be licensed to industry. There is no other reason for a university to obtain a patent, as no university is in the business of making and selling products, and therefore has no proprietary product line to protect.

As most university research is funded by the federal government, one must conclude that PL 96-517 catalyzed and stimulated the whole process, bringing the realization to companies that a truly proprietary position could be established around such inventions through a license agreement with the institution.

IIIa. What universities are leaders in the field?

Table 2: U.S. Patents Issued to
Ten U.S. Universities -- 1988

School	1988	1986-1988
M.I.T.	63	171
Univ. of California	59	181
Stanford	54	135
Univ. of Minnesota	26	70
Johns Hopkins	21	57
Univ. of Florida	21	44
Univ. of Wisconsin	20	48
Caltech	18	68
Univ. of Texas	18	65
Harvard	17	28

About 40 percent of all 1988 academic patents issued to ten universities, which include a balanced number of public and private institutions. The numbers reported for the University of California include those from nine campuses, plus a few based on inventions at three DOE contractor-operated laboratories.

IIIb. What types of academic inventions are patented?

Table 3: Most Active Patent Classes for Academic-Sector Patenting - 1988

Patent class and name	Patents to Academic Institutions	Patents to U.S. Inventors	Academic Share of Patents
	------- Number -------		-- Percent --
Total, all classes	801	40,496	2.0
Total, these 4 classes	257	2,156	11.9
435 Chemistry: molecular biology & microbiology	91	441	20.6
514 Drug, bioaffecting & body treating compositions	80	823	9.7
128 Surgery	47	901	5.2
424 Drug, bioaffecting & body treating compositions	39	432	9.0

See appendix table 5-36 and chapter 6, *Science & Engineering Indicators - 1989.*

The relative importance of drug and biotechnology patents to universities is evident in Table 3. Compare the total of these classes as a percent of patents to academic institutions, with the total of these classes as a percent of all patents issued to U.S. inventors.

IIc. Does the type of invention patented vary from one university to another?

Table 4: Patent Product Mix of Four Universities 1986 - 1988

	Number of Patents Issued			
Class	M.I.T.	U.C.	Stanford	Minn.
All classes	171	181	135	70
Molecular biology	15	33	8	7
Drugs	18	26	10	10
Electricity-Testing	2	26	4	1
Optics	6	—	47	—
Coherent Light	4	1	8	—
Semiconductor Mfg.	10	—	2	1
Stock Material	8	2	1	—
Coating Processes	8	—	—	2
Other	100	93	55	49
% Detailed	42%	49%	59%	30%

Science and Engineering Indicators - 1989

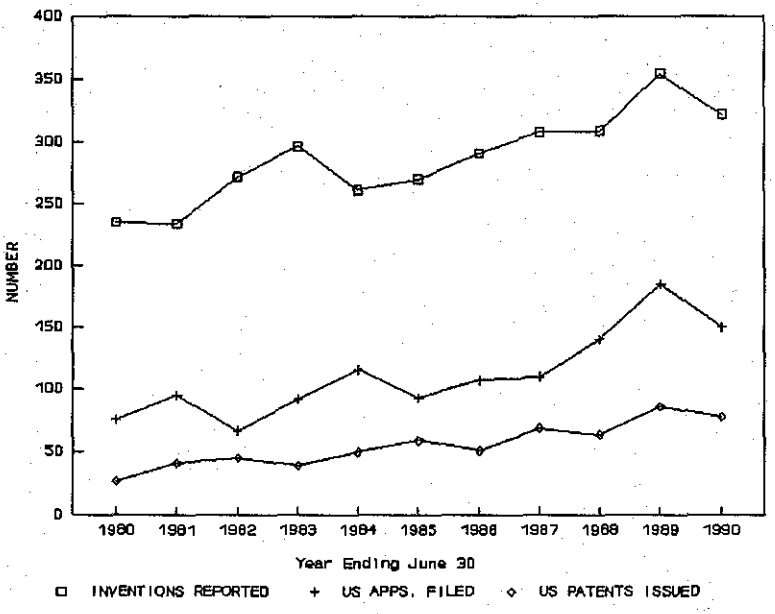
The answer is definitely "yes," as seen in Table 4. Note the variation among institutions. While Stanford's optics portfolio may include several chemical analysis devices, the number of patents in this one Patent Office class is surprising.

IV. What is the bottom line after ten years?

One way to consider this question is to look at changes over time in several descriptor categories from one program. As the data for the University of California cover 3,000

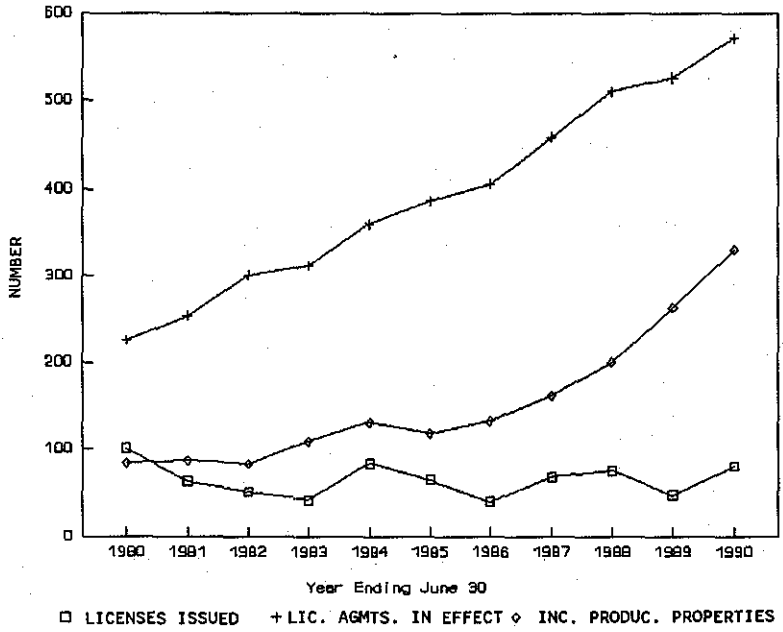
invention disclosures over the last ten years, they may be considered broadly representative of the academic research community.

Figure 2: University of California Patent Activity 1980-90 Disclosures, Applications and Issued Patents.



In Figure 2 the results of a decade of activity are shown as indicated by the number of inventions reported, the number of patent applications filed in the United States, and the number of United States patents issued each year. The data indicate a gradual increase with time rather than dramatic annual increases. With this solid annual base of inventions, licensing activity and income can increase disproportionally, as we see in the following figures.

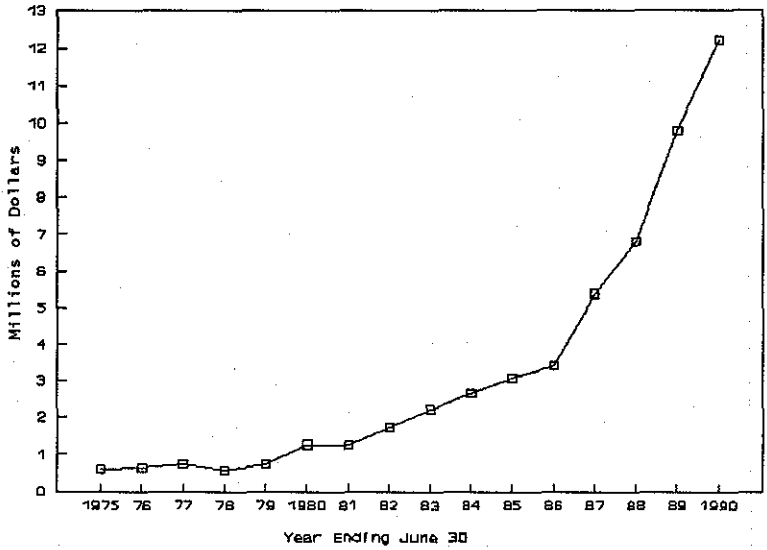
Figure 3: University of California
License and Income Activity



Because inventions are often licensed two or three years before a patent issues, and a patent lasts for 17 years, a few new licenses each year accumulate into a large number of new products under license, all of which are under active development or are on sale. The number of income-producing properties also increases, but the rate of change in the increase lags the issuance of licenses by several years. I will comment more on this very important time lag later.

Income-producing properties produce revenues that build as time passes. If products serving large markets have been licensed, the annual increases in revenue may be dramatic. This has been the case at the University of California, as illustrated by Figure 4.

Figure 4: University of California
Licensing Income 1975-90

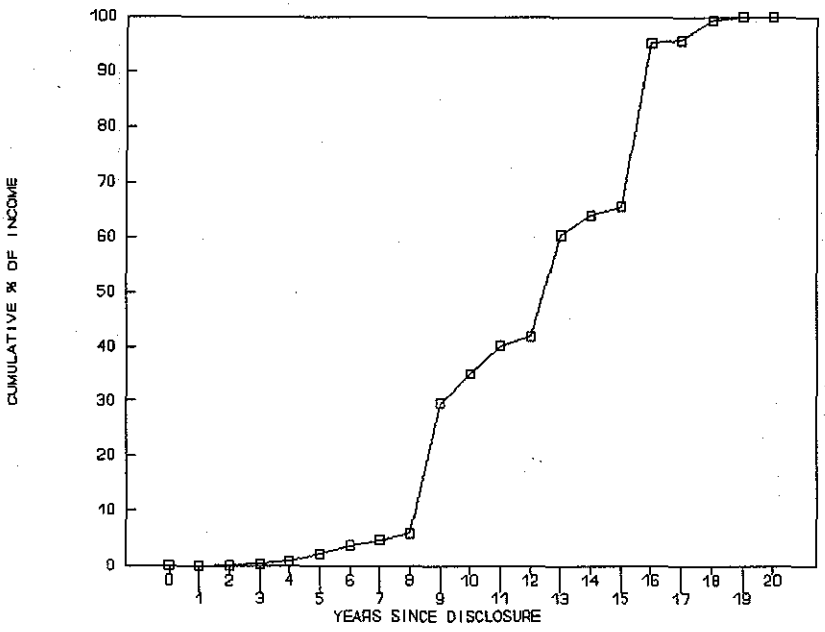


The three distinct stages in program development can be seen in this Figure. The 1975-1979 period represents a stage of extreme understaffing. In 1980, additional staff was added, and the increasing revenues represent license issue fees and the recovery of patenting costs. By 1986, inventions licensed earlier began to generate substantial earned royalty income. Additional staffing in 1987 helped with the workload, but the incremental annual income was of marginal significance in the short term. Income for the year ending June 1991 is expected to be in excess of $18 million*, up from $12.2 in 1990.

The dramatic increase in income in recent years shown in Figure 4 is due to royalties on the sale of products from "older" inventions. Figure 5 illustrates the important "lag time" from disclosure to earned royalty income referred to earlier.

* Author's note: Actual income for the year ending June 1991 was $22.2 million.

Figure 5: Utility Patent Royalty Income
by Age of Disclosure.



In Figure 5, the amount of earned royalty income received in the year ending June 30, 1989, is plotted against the year in which an invention accounting for that income was received. The graph shows that 95% of this type of income is generated by inventions reported eight years ago or earlier. Two-thirds comes from inventions reported ten or more years before 1989, the year from which these data were derived. This significant lag demonstrates that university patent licensing is a "patient money" business. However, the payoff may be large. While it takes eight years for the income stream to develop, remember that it can continue for another twelve years!

In the ten years since the passage of Public Law 96-517, there has been a significant shift in the "product mix" of inventions producing income for the University of California. The mix in 1980 was heavily oriented to agriculture, with only two important income producers related to medicine, as shown in Table 5.

Table 5: Changing Product Mix - I
Inventions Producing Major Earned Royalty Income
1980 - 1989

1980	1989
Desalination Membrane	Agricultural Chemical
Hip Joint	Body Imaging: MR & X-ray
Drug Dispersion Method	Feline Leukemia Test
Strawberries (2)	Strawberries (4)
Sugar Beet Harvester	New Tomato Harvester
Tomato Harvester	Basic Gene Splicing
	Recombinant Drugs & Vaccines

By 1989 the mix had shifted to dominance by medically related inventions, with biotechnology producing substantial revenues. Almost all of these were originally federally funded. Strawberry-related income was not as large a portion as previously. Medical imaging also was a good income-producer.

Table 6 compares the general group characteristics of the seven financially important inventions of 1980 with thirteen of the same class in 1989.

Table 6: Changing Product Mix - II
Inventions Producing Major Earned Royalty Income - II
1980 vs 1989

SEVEN INVENTIONS 1980	THIRTEEN INVENTIONS 1989
$50,000 TO $110,000 EACH	$100,000 TO $1,900,000 EACH
TOTAL OF $580,000	TOTAL OF $6,404,000
45% OF ALL INCOME	65% OF ALL INCOME
84 INCOME PRODUCERS	263 INCOME PRODUCERS

Income for any one invention was
no greater than 20% of total.

The number of income-producing inventions had tripled in ten years. An order of magnitude increase occurred in earned royalty income, as also was the case with the listed-invention income. The income from no one invention accounted for more than 20% of the total income, which is healthy but very atypical of most university patent income profiles. In the more typical case, one or two inventions produce about 80% of income, and the demise of income from one invention can have a catastrophic effect on the program.

While expense for patent applications easily may be greater than income for a given class of inventions in the early years of a program, it is possible to have greater income than expense for many of the classes in the product mix. This is illustrated in Table 7.

Table 7: Changing Product Mix - III
Percent Income and Expense by Product Class

PRODUCT CLASS	% OF INCOME			% OF EXPENSE	
	1983	1985	1989	1985	1989
Chemicals	5	4	5	13	10
Medical Devices	6	9	5	15	10
Drugs	28	4	7	19	16
Recomb. DNA	13	29	50	16	16
Plants	36	44	17	6	10
One % = $000	$22	$31	$98	$13	$28

Detailed examination of this Table should only be undertaken by those with a morbid curiosity for detail or those whose job requires the knowledge of such trivia for survival. The overall ratio of income to expense in 1985 was 2.38 (i.e. $31 divided by $13), but by 1989 the ratio increased to 3.5. In 1989 all classes produced gross income in excess of expense, but in 1985 chemicals and drugs had expense for patenting in excess of gross income. For other classes of lesser importance to income, and therefore not shown, expense did exceed income.

Investments are being made now for the ultimate licensing of inventions in the areas of superconductors, micro-machines, sensors and robotics, and numerous others in the medical area.

Turning now to another aspect of the licensing of university patents, we will comment briefly on the mix of licensee by size and location.

There is much concern in the country at the present time about the competitiveness of our industrial sector. One part

of the concern focuses on whether foreign companies are obtaining the results of federally funded research before they are known to the domestic industrial sector. The General Accounting Office has questioned a number of research universities about their relationship with foreign companies as licensees, sponsors of research, or members of industrial associates programs. The responses are just now being returned, and no results are available yet.

Analysis of the licensee mix at the University of California as of November, 1990, is most encouraging with respect to our ability to license domestic companies.

Table 8: Geographic Location and Business Classification of 212 Utility Patent Licensees
November 1990

LOCATION	
United States	
California	. . . . . 93%
Non-California	. . . . . 57%
Foreign	. . . . . 7%
CLASSIFICATION	
Small Business	. . . . . 87%
Large Business	. . . . . 13%

Of the 212 extant utility patent licenses only 7% were with foreign companies. This did not happen without design and extra work by those doing the licensing, for it is generally recognized that less effort is required in the average case to license a university invention to a foreign company as opposed to an established domestic manufacturing entity.

There is also a natural concentration of licensees in California, but the percentage (87%) of small businesses is higher than might be expected. Ample evidence is provided by this one Figure as to the impact of Public Law 96-517 in connecting risk capital to the university laboratory.

The numbers in Table 8 exclude another 400 licenses to propagators of strawberries and other agronomic cultivars. Almost all of these plant patent licenses are non-exclusive in the United States, but may be exclusive in other countries subject to mandatory sublicensing. But plant licensing is a story in itself, and time does not permit further discussion of that subject except for one comment. The taxpayers of the United States pay for much of the plant breeding research in this country, yet other nations benefit from that research at no cost.

Take for example the "anza" wheat variety distributed without varietal protection after development at the University of California. That variety is widely grown in many countries, including Spain. It is my understanding that most other wheat varieties planted in that country, regardless of source, are subject to a royalty payment. The same is true of cotton seed. Why should the taxpayers of the United States not expect a royalty to be collected on new university-bred varieties, at least on propagation and sale outside the United States? Licensing programs can be designed to the advantage of the university, the industry and the taxpayer.

There is an added benefit to the technology licensing effort at a university that often goes unnoticed. Not only does the ownership of a patent by a university help connect with risk capital for the commercial development of the invention, it also often brings an even greater and more immediate benefit to the inventor's laboratory. That benefit is in the form of funding for more research related to the invention, research that is relevant and proper for the university laboratory where the invention arose. Such sponsored research, under suitable agreements and within appropriate university oversight policies, need not create inappropriate conflicts of interest or prohibit the timely publication of research results.

SUMMARY

What Public Law 96-517 has clearly demonstrated after ten years is that the arguments against retention of patent title by public universities have proven to be invalid and specious.

It has demonstrated that what belongs to all is of interest to no one if substantial risk capital is required for commercial development. It has also demonstrated that taxes flow to the public coffers from totally new products when a university patent is exclusively licensed under appropriate conditions, including an obligation of diligence by the licensee.

In the context of that law, universities have demonstrated that patenting does not inhibit publication. No public university licensing professional could ever tell a faculty member that an article could not be published and expect to keep his or her job. In fact the issuance of a patent is a pretty good publication in and of itself, and there is a great retrieval system.

The question of whether faculty change their line of research to make money through patents is subsumed in why anyone changes a line of research. Most often it has to do with retaining employment, which is certainly a money-making pursuit. And given the low percent of patents that actually make much money, changing the direction of one's research to obtain royalties is like mining fool's gold. It just doesn't pay.

Industry has also demonstrated that it can be trusted and will deal fairly with the university community. After all, the captains of industry are almost all university graduates, are dependent on the university sector for new, highly educated employees, and have no desire to bring the wrath of public opinion down upon themselves through negative publicity about how they mistreated any university.

Risk capital can be attracted to develop new university-invented technologies when and if there is a way to reduce the risk to that capital. University patents are an effective tool for doing just that. While a patent will not eliminate risk, it

will offset that risk through a substantially increased potential reward to the risk-taker.

Industry knows what patents are worth, but many in that sector may not know that it is feasible to get licenses to university inventions that give a competitive advantage. Industry officials respect the talents of university scientists and engineers, but they must be convinced that their risk capital can connect them with those individuals to their mutual benefit.

We need to get this message across to decision-makers in both the industrial and government sectors and to spread the discussion and understanding of the subject within the university sector.

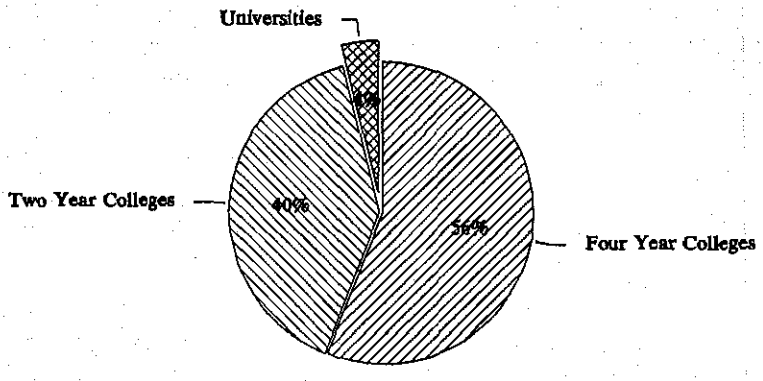
A Decade of Growth

Charles C. Cary*

The purpose of this paper is to document trends in the academic technology transfer process over the last decade, and having done so to predict trends for the coming decade.

ACADEMIC ENVIRONMENT

Figure 1:



U.S. INSTITUTIONS OF HIGHER EDUCATION
3,535 in 1990

Charles C. Cary is Licensing Associate, Technology Transfer Services, State University of New York, Buffalo, NY 14260.

One in twenty Americans is enrolled in an institution of higher education in the United States. As shown in Figure 1, there are 3,535 domestic institutions of higher education. Four percent of these institutions, the universities, offer collegiate, and post collegiate degrees. It is in the ninety-three public and sixty-two private universities that the bulk of the academic technology transfer process originates, because it is through these institutions that the bulk of academic research funding is directed. Geographically, three states -- New York, Texas, and Massachusetts -- are home to over twenty percent of these universities.

University technology transfer came of age in the '80s. In the last decade, there was a dramatic increase in the patent and licensing activity of the universities or of their I.R.C. §501(c)(3) surrogates. Of the 155 universities, the percentage participating in the patenting and licensing process increased from 50% in 1980 to 90% in 1990. The average number of patents granted to universities increased as well, doubling over the last decade, from four per year in 1980 to eight per year in 1990.

LEGISLATIVE FRAMEWORK FOR UNIVERSITY TECHNOLOGY TRANSFER

The private sector has always been capable of benefiting from technology developed within United States universities, but not until this past decade, the '80s, were these universities in so likely a position to benefit financially from that transfer. The primary reason for this change is the enactment of laws which provide for university ownership of inventions arising from federally sponsored research.

PRE-1980

Prior to 1980 there were two paths by which the fruits of academic research were harvested. Academic research, prompted by the requirements for tenure, is generally published. This is in contrast to industrial research which is warrented only if proprietary. Globally, U.S. researchers are

now, and have been for the last decade, authors of forty percent of the scientific articles published worldwide. By comparison, Japanese researchers choose to author less than eight percent of the scientific articles entering the world's datastream.

Second, academic research is disseminated by the steady stream of graduate students entering the job market. It is, after all, this same graduate pool that conducts most of the academic research on which the above-mentioned publications are based. The employment this graduate pool seeks is every bit as diverse as the audience for academic research articles. In 1988 thirty-three percent of all U.S. PhDs were awarded to foreign citizens on temporary visas. At the start of the decade only twenty percent of all U.S. PhDs were awarded to foreign citizens.

Prior to 1980 there was no single codification of the means by which title, royalties, or rights associated with university patents arising from federally sponsored research would be apportioned. Generally, exclusive licenses were not permissible, ownership resided in the sponsoring agency, and universities that did patent had to market those patents using non-exclusive patent licenses, an oxymoron. One can posit that exceptions to the rule were required before private industry could be induced to focus its attention on the public domain technology developed in universities, as opposed to the proprietary technology developed in its own laboratories. Indeed, The Wisconsin Alumni Research Foundation, an arm of the University of Wisconsin, had as early as 1968 entered into a blanket agreement with National Institutes of Health that provided for the grant of exclusive licenses of patent rights. In 1973 that same university entered into a similar agreement with the National Science Foundation. These agreements, and the facility they added to the technology transfer efforts of the University of Wisconsin, were in 1980 codified into a law from which all universities were to benefit.

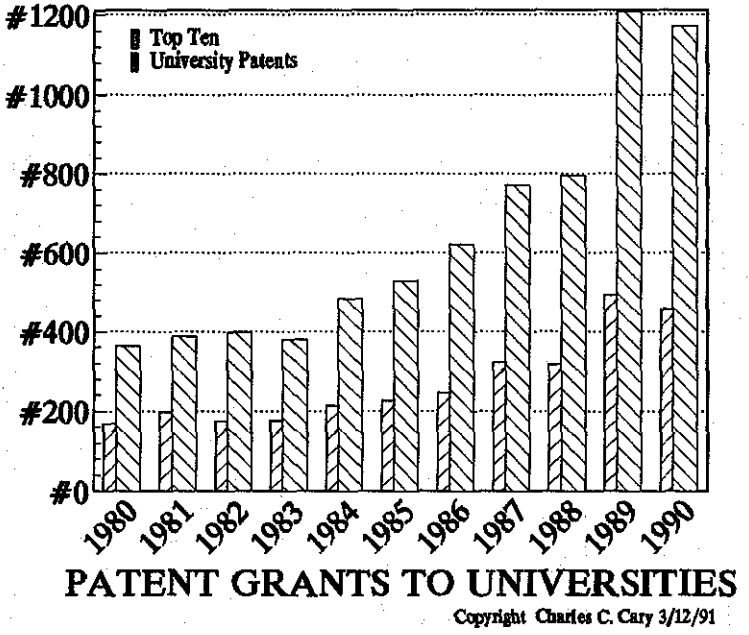
POST-1980

The third phase of university technology transfer began in ernest with the Congressional enactment of Public Law 96-517 on December 12, 1980. This legislation provided specific additions to title 35 of the United States Code, dealing with patent rights in inventions made with Federal assistance. It allowed universities and non-profit institutions to elect to retain title to inventions made under government sponsorship, and provided for exclusive term-of-patent licenses. These full term exclusive licenses were initially limited to small business licensees. Succeeding legislation, specifically Public Law 98-620, enacted November 8, 1984, gave universities the right to grant exclusive term-of-patent licenses to any business, small or large, foreign or domestic, provided:

> "[S]uch person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. "

The impact of the above-mentioned legislation was a dramatic increase in the patenting activity of universities during the decade. What had been a trickle of patents averaging three hundred per year in the '70s became a torrent in the '80s. As is shown on the accompanying Figure 2, patents issued to universities increased at approximately 14% per year throughout the decade.

Figure 2:



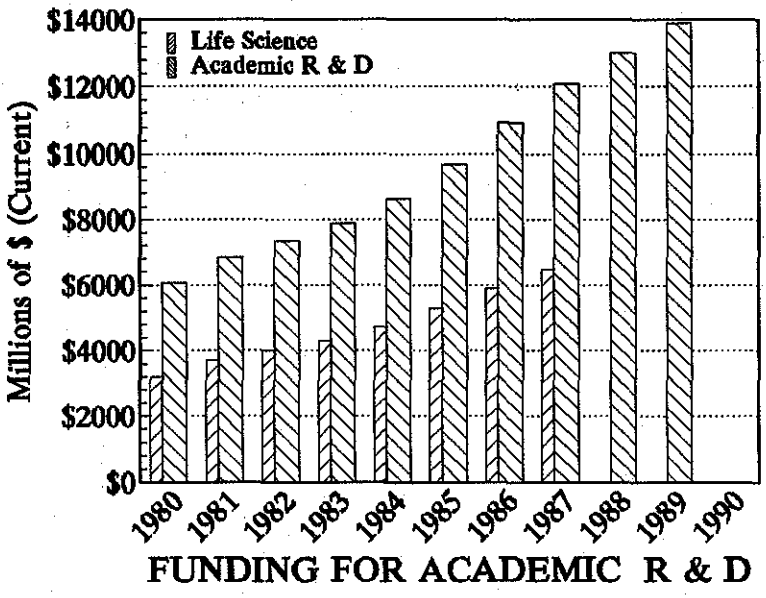
FISCAL FRAMEWORK FOR UNIVERSITY TECHNOLOGY TRANSFER

The federal government provided six out of every ten of the research dollars expended by universities in 1989 and at the time P.L. 96-517 was passed in 1980, this ratio was even higher. Were it not for the fact that federal support for academic research is so substantial a portion of total academic research funding, the impact of the above-mentioned legislation would not have been so visible.

Overall research expenditures in the United States grew steadily at about 9% per year during the decade. In 1989 overall research expenditures exceeded $132 billion, or approximately three percent of Gross National Product. The federal government was then, and continues to be, an engine

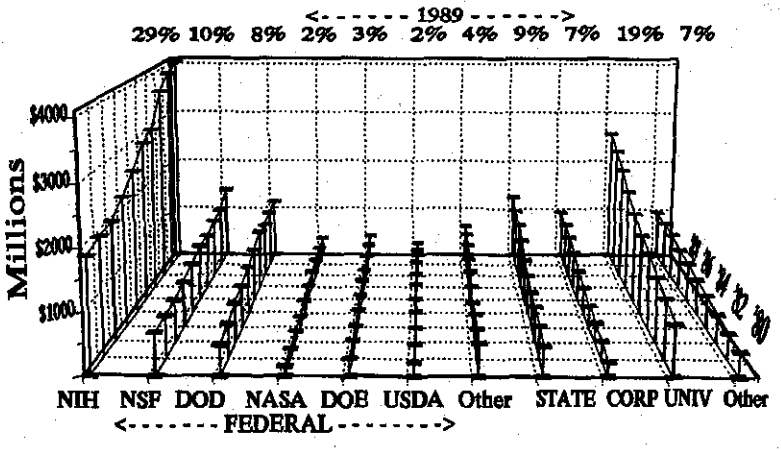
for research funding in the United States, providing one dollar in research funding to every dollar spent by industry.

Figure 3:



While the bulk of these federal research dollars are directed to industry and while the bulk of industrial research dollars stay in house, there is nevertheless a small portion of each dollar, 13% of the federal and 1.5% of the industrial, that comprises the bulk of the funding for university-based research. As is shown in Figure 3, university research funding exceeded $13 billion in 1989, having increased at 10% per year during the decade.

Figure 4:

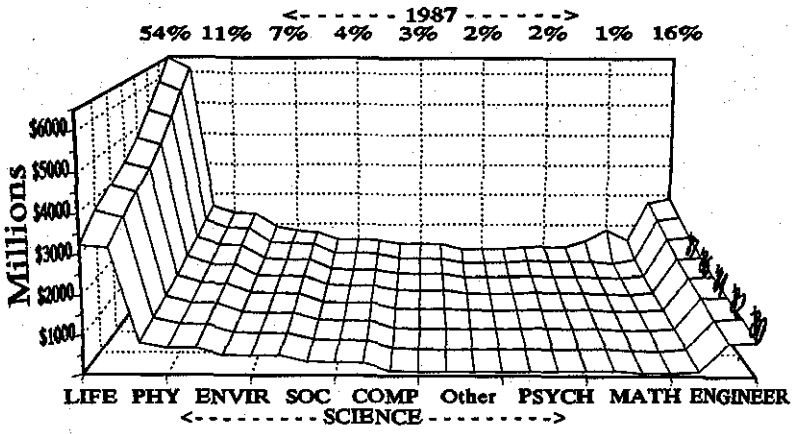


"A DECADE OF GROWTH"
***FUNDING* of ACADEMIC R & D 1980-1989**

As is shown in Figure 4, the federal portion of academic research funding is dispensed by a handful of agencies, of which the National Institutes of Health is the most significant, accounting for over $4 billion in funding for academic research in 1989. This single agency's expenditures accounted for over 29% of the academic research funding in that year. Growth rates in federal agency funding of academic research (8% per year) lagged behind the overall growth rate of academic research funding (10% per year), for the decade. The healthy growth of academic research funding is due to above-average annual funding increases in research funds derived from the universities themselves and from industry. At the start of the decade $14 out of every $100 in academic research funding came from the universities. By the close of the decade universities self-funded $18 out of every $100 in academic research. This shift was a result of a 13% annual growth rate in self-funded research over the decade. In 1980, $4 out of every $100 in academic research funding

came from industry. At the close of the decade industrial contributions accounted for $7 out of every $100 in academic research funding. This shift was a result of a 16% annual growth rate in industry-funded academic research over the decade.

Figure 5:



TYPES OF RESEARCH FUNDED

Funding for academic research is highly focused. The fiscal policy of the federal government is evidenced in the actions of its funding agencies, which are prepared to respond to only a narrow range of proposals from university faculty. As is shown in Figure 5, the primary research area during the decade was the life sciences. In 1987, the last year of record, funding for the life sciences accounted for 54% of all academic research funding. The life sciences encompass biology, medical sciences, and agriculture. Running a distant second with 16% of the total in 1987 are the engineering disciplines. These include metallurgy, aeronautical, electrical, mechanical, chemical, astronautical, and civil.

UNIVERSITY PATENTS

Considering the focused nature of academic research funding, it should come as no surprise that the subject matter of university patent grants mirrors the subject categories to which research funding is directed. The following Table 1 indicates the top ten subject areas in which universities were granted patents for the decade. The categorization is derived using the same classification numbers that the United States Patent and Trademark Office uses for each patent it examines. The body of the table lists the number of patents issuing to universities each year during the course of the decade in each of these classes. Out of the 7,180 patents issued to universities during the decade, over 33% of them issued in the first five classes listed in the table. The subject matter of these classes is the life sciences.

Listed in the bottom row of Table 1 are percentage figures representing the proportion of patents granted to universities in these ten categories as a percentage of all patents issued to universities. The ratios are relatively constant, and indicate that one out of every two patents issued to universities is in one of the top ten subject areas.

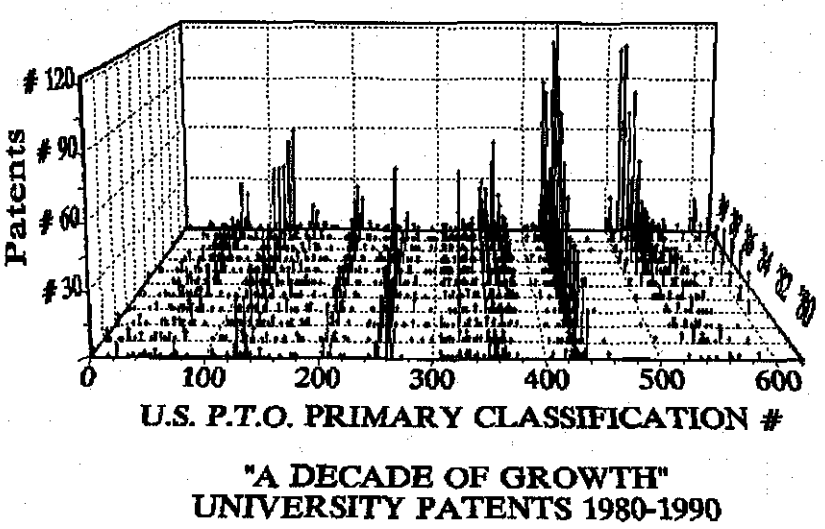
Although patents issuing to universities constitute a relatively small though increasing percent of all patent grants, approximately 1.2%, the universities can be major contributors to the patent art in certain subject areas. In class 435, "Chemistry: molecular biology and microbiology," for example, University patents accounted for 8% of all issuances in this subject area, up from 4% at the start of the decade. Less dramatic increases were evidenced in all of these top ten categories.

Table 1: Leading Subject Matter of U.S. University Patents Itemized by U.S.P.T.O. Primary

U.S. P.T.O. CLASS #	'80	'81	'82	'83	'84	'85	'86	'87	'88	'89	'90	TOTAL
CHEM-MOLECULAR BIO 435	22	30	36	33	31	32	58	81	97	123	111	654
DRUG, BIO-AFFECTING 424	43	44	61	56	79	19	32	50	38	85	88	595
DRUG, BIO-AFFECTING 514	--	--	--	--	--	39	59	92	77	112	107	486
SURGERY 128	26	20	29	21	34	30	54	40	47	56	59	426
CHEM-CARBON CMPD 260	32	43	21	16	28	29	12	4	6	4	--	195
ELEC.COMPUTERS 364	5	5	5	3	12	9	10	17	16	56	39	177
MEASURE & TEST 73	7	9	10	11	16	23	18	18	13	31	20	176
RADIANT ENERGY 250	7	8	14	5	11	9	9	13	23	40	36	175
MEASURE & TEST 324	3	5	11	6	9	5	15	27	22	39	29	171
OPTIC-SYSTEMS 350	6	5	4	6	6	17	15	13	27	33	24	156
TOTALS	151	169	191	157	226	212	282	355	366	579	513	3211
% of ALL UNIV.PATENTS	42%	44%	48%	41%	47%	40%	45%	46%	46%	48%	44%	45%

As is shown in the following Figure 6, universities are minor players in all other subject areas. Figure 6 incorporates

Figure 6:



information on approximately 7,000 patents assigned to universities during the last eleven years. The horizontal axis corresponds to the U.S. Patent and Trademark Office patent classification number associated with the primary examination group listed on the front page of each patent. This gives an indication of the specific subject area in which universities are procuring patents. The axis running into the page is the time-line, with the year 1980 being in the foreground and 1990 the backwall. The vertical axis represents the number of patents by universities in each examination group in each year. The reader will note the intense congregation as well as growth in the number of filings in the top ten classes referred to in Table 1. Otherwise, there is a general blanket of filings in many subject areas with little or no growth in issuances during the decade.

Table 2 indicates the ranking of universities on the basis of their patent grants during the decade. Collectively these top ten universities accounted for 42% of all patent grants to universities during the period. They were also the recipients of 25% of all academic research funding in the last year of record, i.e. 1987.

The ranks of the top ten have changed little since the start of the decade. Seven out of the ten universities that led in patent activity at the start of the decade finished in the top at the close of the decade. The three new entries were the Universities of Texas, Minnesota, and Florida, which replaced Purdue, Utah, and Illinois. Even among the top ten, there is little consistency in patent grants, as exhibited in Figure 7.

Figure 7:

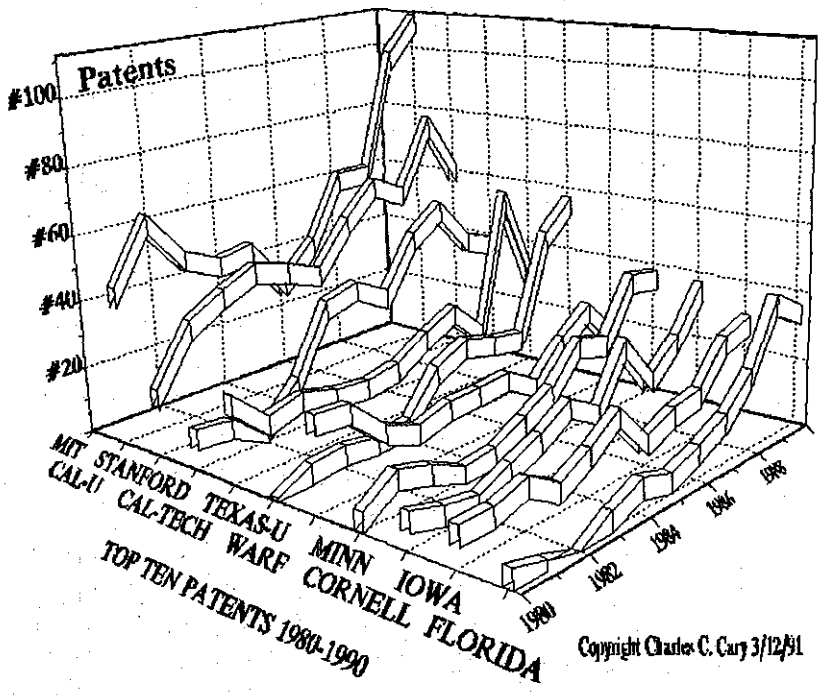


Table 2: Universities granted the greatest number of patents 1980-1990.

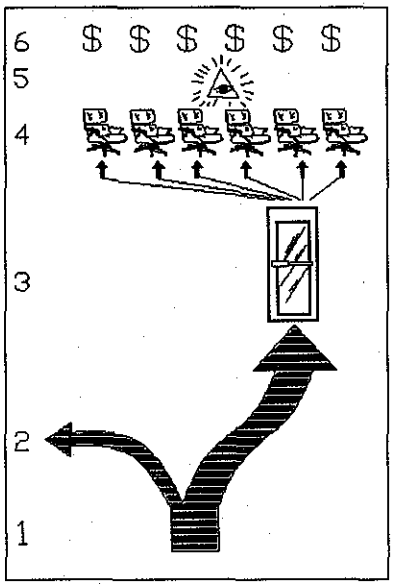
	'80	'81	'82	'83	'84	'85	'86	'87	'88	'89	'90	TOTAL
MIT	47	66	52	47	49	35	45	64	64	100	111	680
CALIFORNIA UNIV. OF	20	37	43	48	45	41	54	64	59	80	62	553
STANFORD	12	11	5	16	36	39	33	49	56	43	39	339
CALIFORNIA INS. TECH	26	16	19	16	15	17	23	28	18	59	30	267
TEXAS UNIV. OF	1	6	7	5	7	19	24	21	19	48	57	214
MINNESOTA, UNIV. OF	6	13	10	5	6	11	16	27	24	40	38	210
WARF	28	27	17	13	16	16	17	11	21	28	16	196
IOWA STATE UNIV.	12	12	15	9	14	21	9	13	15	27	30	190
CORNELL	11	8	6	10	14	20	14	30	16	24	37	177
FLORIDA UNIV. OF	6	3	0	6	10	7	10	15	24	42	36	159
TOTALS	169	199	174	175	212	226	245	322	316	491	456	2985
% of ALL UNIV.PATENTS	47%	52%	44%	46%	44%	43%	39%	42%	40%	41%	39%	42%
UNIVERSITY PATENTS	362	386	398	380	483	529	622	772	795	1208	1171	7106

DECISION-MAKING APPARATUS FOR TECHNOLOGY TRANSFER: ANATOMY OF TWO OFFICES

Up to this point we have been analyzing statistically the performance of Universities in the aggregate. From this point hence we will engage in a more subjective look at specific organizational and structural features of the technology transfer process, and to this end we will look at the technology transfer process at Stanford University ("S.U.") and the University of Texas System ("U.T."). Granted, there are as many methods of configuring a technology transfer function as there are universities, but, for purposes of comparison, no two universities provide more striking contrasts than the operations at S.U. and U.T.

STANFORD University

Figure 8:

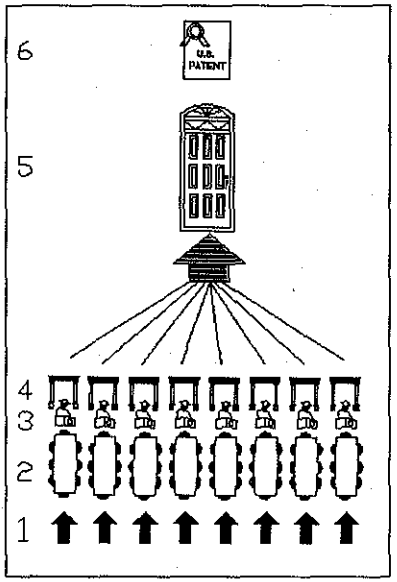


S.U. has a single campus, and the technology transfer function is performed by a 501(c)(3) corporation based on that campus. Because the faculty inventor has complete ownership and control of inventions not arising from federally sponsored research, a small percentage of the inventive activity on the campus is not processed by the technology transfer office (Figure 8: Step 2). Those disclosures that are made to the office are assigned to a specialist (Figure 8: Step 4). The specialist will typically have a bachelors degree in a technical discipline as well as several years of experience in industry. The specialist is responsible for creating a marketability opinion, including a projection of the royalty stream. Each specialist operates as an independent

profit center, with complete responsibility for marketing the subject invention on the basis of patent, copyright, or proprietary intellectual property protection. The paradigm for the organization is marketability (Figure 8: Step 5). All specialists are evaluated quarterly on the basis of their royalties (Figure 8: Step 6).

University of TEXAS

Figure 9:



The U.T. system consists of fourteen separate component institutions, all of which evaluate disclosures by means of campus-based faculty committees (Figure 9: Step 2). The faculty committees in turn make a recommendation to the president of the subject campus, and the president's office forwards the recommendation to the system's Office of General Counsel (Figure 9: Step 5). One individual at this office, a patent attorney with over 20 years experience, then makes a final evaluation and assuming a favorable opinion, proceeds to authorize outside counsel to file a patent application. Each campus has autonomy to pursue licensing and commercialization efforts.

As is shown in Table 3 there are striking differences in the royalty stream of the two organizations. S.U.'s lump-sum royalty came from a negotiated licensing effort with AMGEN. U.T.'s lump-sum royalty payment came from a post trial, pre-verdict settlement with a patent infringer. S.U.'s running royalties were seventeen times those of U.T., and even after subtracting S.U.'s Cohen-Boyer royalties there is still a seven-to-one difference in royalties. Viewing these two operations, it is difficult to avoid the conclusion that there is a direct correlation between royalties and marketing

Table 3

Figures are for 1990	Stanford U.	Texas U.
Ownership of inventions not arising from federally funded research	Inventor	University
Inventor's share of royalties (after 3rd party costs)	28%	50%
# of Campuses	1	14
Research Funding (1987)	$241 mil.	$407 mil.
# of Disclosures	150	300
# of U.S. patent applications	25	110
% with foreign filings	30%	30%
# of patents granted	39	57
% of all patents held under license	50%	25%
% of royalties from foreign source	8%	0%
Lump Sum royalties	$4.5 mil.	$5.6 mil.
Running Royalties	$21.5 mil.	$1.3 mil.

effort. Of course, one has to keep in mind the fact that the program at U.T. is younger than that at S.U. U.T. started off the decade with one patent; S.U. with 12.

PREDICTIONS

The wellspring for technology transfer is research funds. There are many reasons for predicting a decline in the rate of increase in research funding for the coming decade. Foremost among these is the enormous federal deficit, which, when steps are inevitably made to reduce it, will require a paring of agency budgets. States no less than the federal government are undergoing their own fiscal crisis. The combined twenty billion dollar shortfall in the budgets of New York, California, and Massachusetts does not bode well for state-funded research at universities in those states.

However much these shortfalls affect the research process, or, for that matter, the budgets of the technology transfer offices at the various universities, the impact on the royalty stream of the universities probably will not be felt until the beginning of the next century. There are two reasons for this. First, many of the licenses that universities have in place have not yet hit their stride in terms of royalties. Many of the products to which they pertain have not yet hit the market, i.e. are still in the Food and Drug Administration (F.D.A.) pipeline. When these do hit the market they will have a full seventeen year royalty life extending well into the next decade, thanks to the patent term extension act. The second reason for expecting royalties not to be immediately affected by a decline in the growth in research funding is that university technology transfer offices still have room for improvement in the amount of royalties they generate as a percentage of research funding. Improvements in this area should therefore offset the effect of declines in the rate of growth of research funding. In sum, I predict steady increases in university royalty revenues during the next decade.

A unique confluence of technology and legislation during the '80s has resulted in universities being vested with a large role in the development of what is currently an infant

industry, namely biotechnology. Biotechnology came of age in a university setting and to a large degree industry still relies on universities for new products to expand the breadth of the industry. Viewed in this light, the "manufactured substantially in the United States" requirement of Public Law 98-620 is about as close to an industrial policy as this government is likely to commit to in the near future. Assuming that all university licenses arising from government sponsored research contain restrictions identical to those called for in P.L. 98-620 and assuming further that those restrictions are interpreted broadly to require substantial manufacturing in the U.S. for foreign as well as domestic sales of the subject invention, then there is every reason to expect that a good portion of the manufacturing associated with this developing industry will remain on these shores.

Failing that, I predict the following countervailing factors will produce a climate in which the U.S. biotech industry, when it does come of age, will have no more domestic flavor to it than robotics or semi-conductor chips currently have.

1) The biotech industry is very small and vulnerable. In 1990 the sales of the domestic biotech industry, comprised of 1150 companies, were estimated by the Department of Commerce at approximately $2 billion dollars. For purposes of comparison, this figure is 25% of the sales of the popular video games provided by Nintendo and less than 2% of the sales of automobiles in this country. Alternatively, the market capitalization of the fourteen leading U.S. biotech companies is approximately one-tenth of the current yearly trade surplus between Japan and the U.S.

2) The pathways for marketing and market allegiances in pharmaceuticals and biotech are not dissimilar, and Japan has the world's highest per capita consumption of drug products, followed by the United States. Furthermore, in absolute terms, the Japanese pharmaceutical market accounts for approximately the same share of the world market as does the U.S. (23% vs. 27%).

3) The Japanese have a proactive investment policy, and the United States does not. In Japan, for example, "foreign ownership of more than ... 25% of its 'technologically innovative companies,' is flatly prohibited..." M. & S. Tolchin, Buying into America, (Times Books 1988) at 224. In the U.S. there is no *per se* restriction of foreign ownership of domestic corporations, though under the Trade and Tariff Act of 1984 and the Omnibus Trade and Competitiveness Act of 1988 respectively, there are vehicles putting economic pressure on foreign governments that burden direct investment or for reviewing takeovers that impair the national security. Unfortunately, no biotech company has been a beneficiary of either policy, as sales such as the 1990 sale of a controlling interest in Genentech to a foreign corporation, Roche, confirm.

4) Aside from the availability of foreign capital there are other reasons why foreign corporations are getting a leg up in biotech. More and more clinical testing of new drugs is being done overseas. This is because of the combination of strict regulation of domestic trials by the F.D.A. and the willingness of that organization to accept foreign trials in partial satisfaction of licensing requirements here in the U.S. "Although a considerable amount of human experimentation has been done in Japan, neither the Japanese government nor the Japanese Medical Association has promulgated a code of ethics governing experiments on human beings, nor was there an institution providing general guidance for such experiments." Bassiouni *et. al.*; An Appraisal of Human Experimentation...," The Journal of Criminal Law and Criminology, Vol. 72, No. 4, Winter '81, 1597-1666, at 1647. It should come as no surprise that at this point twenty-five percent of the new drugs in the F.D.A. pipeline are coming from Japan. Venture, January 1989, at 28.

5) Domestic sales alone will not be enough to foster a strong biotech industry. If our emerging companies are to market abroad they will have to rely on international intellectual property protection in order to establish a foothold in foreign markets. These protections are far from uniform. Japanese patent laws make it impossible to gain the sort of quasi-monopoly position that can be provided by U.S. patents. "Under the Japanese patent law there are ... compulsory licenses ... based on necessity from the public interest (Article 93) ... [and] demand from the owner of a dependent patent (Article 92)." Eisen *et. al.* "Claiming Biotechnological Inventions, A comparative review of the practice in Europe, Japan and the United States," (Chemical Practice Committee, American Intellectual Property Law Association, May 1985, at 5).

Product Liability Risks of Licensing and How They Affect Commercialization of University Research -- Is It Time for a Legislative Solution?

Jerald E. Rosenblum*
and
Kathy A. Fields**

This paper first explores the current state of the law regarding the application of the doctrine of strict product liability to technology licensors,[1] and then discusses its effect on university licensing activity, particularly under the Dole-Bayh Act.[2] Finally a legislative initiative is proposed.

STATE OF THE LAW

Beginning in the early 1960's, the state courts have created a new common law doctrine under which all persons and entities with a significant participation in the introduction of a product into the stream of commerce are strictly liable for injuries caused by that product. Previously liability attache

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* Rosenblum, Parish & Bacigalupi, P.C., San Francisco and San Jose, CA.

**J.D. Candidate May 1991, Stanford University.

attached only upon negligent failure to exercise due care or upon extension of a contractual product warranty.

An examination of several cases applying and interpreting the doctrine of strict liability incorporated in state product liability law illustrates the uncertainty that technology licensors face. These cases provide some indication (and sparse comfort) regarding the probability that such licensors will be held strictly liable in either a third-party suit for indemnification or an action brought by a person injured by a product embodying the licensed rights.

In imposing strict liability on a trademark and technology licensor, the California Court of Appeals articulated the "stream of commerce" basis for liability that has been followed in numerous jurisdictions. *Kasel v. Remington Arms Co.*, 24 Cal. App. 3d 711 (1972). *Kasel* was an action by a person injured by a defective shotgun shell that had been manufactured in Mexico under a license from the defendant. In this case the defendant (1) caused the manufacturing entity to be created, (2) entered into three contracts with the licensed manufacturer,[3] (3) owned forty percent of the outstanding stock of the manufacturer, (4) created common and interlocking officers and directors, and (5) benefitted financially from the arrangement. In light of these relationships, the court felt that the trial court should have found as a matter of law that Remington was an integral part of the enterprise that placed the defective shell in the stream of commerce. *Id.* at 723.

The court went on to discuss the development of product liability in California jurisprudence. First the court noted that strict liability was appropriate in *Kasel*, as that type of liability should be imposed upon the overall enterprise responsible for placing defective products in the stream of commerce. The court then acknowledged that strict liability actions had typically involved a downstream retailer,[4] and that strict liability had not previously been applied upstream to a franchisor (*i.e.*, to a licensor permitting the licensee to use its trademark and business methods). *Id.* at 724. After examining the relationship of the defendant to the manufacturer and the benefits accruing to the defendant from this relationship, the court concluded that strict liability was

appropriate in this case where Remington had been an active participant in the enterprise bringing the product to market, and as such had been more involved than a typical downstream retailer who could be held strictly liable.

The expansive stream-of-commerce form of enterprise liability was applied again by the California Court of Appeal in *Fortman v. HEMCO*, 211 Cal. App. 3d 241 (1989). *Fortman* was an action on behalf of a three-year-old girl who was permanently injured after being ejected from a moving jeep and struck by another vehicle. The girl had inadvertently opened the door of the jeep, which was part of a fiberglass jeep top. The plaintiff argued that the door was defective due to its rear-hinged and front opening design and exposed door handles. The plaintiff had settled with all parties but HEMCO, and the Court of Appeals affirmed the determination in the lower court that HEMCO was 25% responsible for the injuries and upheld the accompanying jury award of $23,742,620.

The jeep top had been designed and actually produced by other parties. HEMCO was paid $2500 to produce the fiberglass mold for the top from a prototype built by another party and cast two tops (neither of which were involved in this accident). HEMCO's bid to manufacture the top had been rejected. The president of HEMCO (Hill) had advised the inventor on issues related to the door but Hill was not consulted on the placement of the door hinge. Meetings attended by Hill, the inventor, and the person building the wooden prototype were held to discuss the construction of the prototype. The top involved in the accident had been cast from the mold produced by HEMCO.

The court in *Fortman* reaffirmed the stream-of-commerce approach to enterprise product liability after noting the loss and risk spreading rationale for strict liability. The court held that entities deemed to be in the stream of commerce were not limited to readily identifiable designers, manufacturers, or vendors, and that participation, not control, is the determinative factor in assessing liability. *Id.* Therefore HEMCO's defenses, asserting it had no control and that it was not responsible for placing the top in the stream of commerce, were rejected. The court viewed the production

of the mold as an essential step in bringing the defective door to the market. *In dicta* the court indicated that a defendant could possibly avoid liability by showing that it was not in the business of selling or leasing the defective product. In the instant case the court ruled that this defense was unavailable to HEMCO, as it was in the business, making fiberglass molds and products cast from such molds. It seems that this defense would be available in very few situations, given the court's willingness to impose liability on HEMCO, which did not sell or lease an injury-causing product.

The Court of Appeals for the Ninth Circuit also applied a broad enterprise liability, with a focus on the control involved, in *Torres v. Goodyear Tire and Rubber Co.*, 901 F.2d 750 (9th Cir. 1990), opinion by Arizona Supreme Court at 163 Ariz. 88 (1990). In that case the federal court certified the following question to the Arizona Supreme Court and received an affirmative response: Is strict liability appropriate for a trademark licensor significantly involved in the overall process by which the product reaches consumers? The action was for injuries resulting from an accident caused by tread separation on a Goodyear tire that had been designed and manufactured by foreign subsidiaries of Goodyear. The licensing contract provided that the tires must be manufactured in accordance with formulas and specifications given by Goodyear, produced from materials provided by Goodyear, and labeled, marketed, packaged, and advertised according to Goodyear instructions.

The Arizona Supreme Court rejected any reliance on the definition of manufacturer or seller provided in Restatement of Torts Second § 402A, and instead looked at the ability of Goodyear to control production and design of the tires. The reservation of the ability to control provided a basis for liability and the court found it unnecessary to look for a showing of actual exercise of control. After quoting *Prosser and Keaton on the Law of Torts* § 100 (5th ed. 1984) on patent licensors, the court indicated *in dicta* that strict liability may be inappropriate for a "mere licensor"of a trademark or patent. As this question was not before the court, it declined to decide that question or to provide any definitions or guidelines. Finally the court noted that recognizing a

distinction between Goodyear and its foreign subsidiary when a tire is labeled Goodyear would surprise consumers.

In a similar situation involving personal injuries resulting from tire failure, the Supreme Court of Illinois based the imposition of strict liability on the trademark relationship itself. *Connelly v. Uniroyal Inc.*, 75 Ill. 2d 393 (1979). In *Connelly*, the plaintiff brought suit against Uniroyal for damages caused by a tire manufactured in Belgium by a wholly-owned subsidiary of Uniroyal. The court rejected both vicarious liability premised on the ownership and control by Uniroyal, as used in *Torres*, and the recharacterization of Uniroyal as a seller as basis for imposing strict liability. Rather the Supreme Court of Illinois, quoting *Kasel*, ruled that strict liability was appropriate in this case, as the tire bore the trademark of Uniroyal. The court also endorsed the public policy rationale of strict liability for trademark licensors given in Kasel.[5]

The issue of strict liability for a trademark licensor also arose in *Carter v. Joseph Bancroft & Sons Co.*, 360 F. Supp. 1103 (E.D. Pa. 1973). *Carter* involved a motion by the defendant for judgment notwithstanding the verdict following a finding of liability for personal injuries sustained by the plaintiff when her dress caught fire. The defendant here prescribed and controlled specifications and quality standards for the dress that bore its trademark, which had been manufactured by another company. A tag in the dress stated this fact. The court found unpersuasive the arguments by the defendant that it was a mere licensor, and not a "seller" for purposes of imposing strict liability under the laws of Pennsylvania. The court ruled that the defendant was sufficiently involved in the manufacturing process to be deemed a seller and thus subject to strict liability. The opinion does not discuss the degree of control actually exercised by the defendant, but does note that the tag, available to the plaintiff (consumer), indicated that control was exercised. *Id.* at 1106. This representation could have induced reliance on the part of the plaintiff and provides support for the imposition of strict liability.

These three cases, *Torres*, *Connelly*, and *Carter*, illustrate the three theories commonly used to impose strict

liability in a trademark licensing situation. *Torres* used vicarious liability based on control. *Connelly* based the imposition of strict liability on the trademark licensing. Finally, the characterization of the licensor as a "seller" was involved in *Carter*.

Another federal court interpreting state (Kentucky) law imposed strict liability for a failure to warn on a defendant that was neither a seller nor a manufacturer in *Taylor v. General Motors*, 537 F. Supp. 952 (E.D. Ky. 1982).[6] In that case, an action was brought by the widow of a plaintiff who had been killed by an engine blade that had detached from a running motor and struck the plaintiff in the chest.[7] The plaintiff's cause of action was based on defective design and a failure to warn. The Court of Appeals granted the plaintiff's motion for new trial following a jury verdict for General Motors (GM) because the trial court had refused to give an instruction on strict liability.

In *Taylor*, no precise legal relationship existed between GM and the actual manufacturer of the blade, and the blade bore no markings linking it to GM. Furthermore, there was no proof that the actual injury-causing blade had passed through GM's hands. The blades were manufactured by Hayes-Albion (H-A) and sold to GM (99%) and Checker Motor Company (1%). Based on the following, the court declared that GM was "intimately involved" with the manufacture of the blades: (1) GM had given the manufacturer a sketch of the blade it wanted produced; (2) GM approved the manufacturer's actual design before any blades were produced; (3) in 1986, GM redesigned the blade; (4) GM decided when production should be discontinued; and (5) GM had suggested that the manufacturer sell the blades to the only other user, Checker Cab. The court decided that this relationship was a type of franchise without the use of a tradename, and that GM had controlled design and testing and was therefore an integral part of putting the blade in the stream of commerce. The court went on to rule that GM had the duties of a seller in this case and therefore had a duty to warn. This liability was imposed despite the fact that GM's tradename was not used on the blade, and that consumer reliance and expectations were lacking. The plaintiff in *Taylor*

mixed and matched parts in cars for which the part was nottested; there is no discussion by the court of whether this action by the plaintiff was intervening negligence or foreseeable use.

The Supreme Court of Connecticut reached the opposite conclusion in an analogous situation involving a third party suit for indemnification. *Burkert v. Petrol Plus*, 216 Conn. 65 (1990). *Burkert* was an action by Petrol Plus for third-party indemnification from General Motors (GM) for damages allegedly caused by defective transmission fluid that had been licensed under GM's trademark, Dexron SM II. As phrased by the court, the issue on appeal was "must a licensor of a trademark indemnify the distributor when the licensor did not participate in production, marketing or distribution?" After discussing GM's involvement with Dexron (the product) and Petrol's various theories of GM's liability , the court ruled that GM was not liable for indemnification.

The court started with a discussion of GM's "unusually limited" role as licensor. In this case GM licensed its trademarks for products formulated by other companies; these products were required to meet an initial qualification performance test but were not subject to any continued testing or control by GM. Furthermore, GM received no royalties or financial benefit from this arrangement. GM's stated rationale for this set-up, one apparently believed by the court, was that GM wanted to ensure a supply of high-quality transmission fluid. Throughout the opinion the court emphasizes that GM had no control over the formulations, production, labeling, or distribution.

Although not discussed in the court's opinion, several unique facts may have influenced the outcome in this case. First, this case does not involve a product that was unsafe or defective in a way that was unknowable, rather the defect was precipitated by a wrongful act committed by Atlantic.[8] This intervening tortuous conduct may have relieved GM of responsibility. Next, GM was not alerted by Petrol when complaints first surfaced. Petrol sent the fluid to be analyzed at a lab that was not a GM-approved testing lab. This lab, in the first analysis, erroneously determined the fluid was "satisfactory for use". Again, this action by Petrol deprived

GM of notice of possible problems and a chance to take any corrective action. Finally, the fact that GM licensed a trademark for formulations developed by others may have been a strong indication that GM had neither a product or an invention to sell or to license.

In an analogous situation, the Court of Appeals of Arizona ruled that a broker who exercised no control over a product was not strictly liable under the enterprise theory. *Dillard v. Associated Merchandising Corporation*, 782 P.2d 1191 (1989). In *Dillard* the defendant was a broker that had been set up by a group of department stores to provide buying services and merchandise management. Associated Merchandising Corporation was awarded summary judgment in an indemnity action brought by Dillard after a consumer injured by a defective piece of luggage had filed a claim against Dillard. While the broker did bring together buyers and sellers, it lacked the attributes of a traditional retailer . For example, the broker did not sell, manufacture, distribute, or license the product. Furthermore, the broker never owned or controlled the product, and in fact, never made a profit from the arrangement.

After examining this relationship to determine the degree of control exercised by the defendant, the court ruled that the broker was in the stream of commerce but lacked the "participatory connection" required for liability. The court noted that enterprise liability should be used when an entity receives an economic benefit or to encourage an entity in the position to take preventative or remedial action to do so. In *Dillard*, the broker had no opportunity or ability to affect the design or specifications or to inspect the product. While not mentioned in the court's opinion, there were other parties, such as the department stores, that were in control and better situated to perform these functions. Finally, the actions or involvement of the broker induced no consumer reliance or expectations.

While no clear standard for the degree of involvement that triggers the imposition of strict liability under the enterprise theory can be gleaned from this case law, some common factors in these cases provide an indication of what

types of behavior and licensing agreements will result in liability. These factors include the following:

(1) the relationship of the defendant to the product causing injury *i.e.*, the role of defendant in putting product in "stream of commerce";

(2) the stated rationale for imposing strict liability;

(3) the type of defect and defendant's action relative to the defect;

(4) intervening acts of other parties; and

(5) consumer expectations.

No single factor is determinative of liability. While present in most cases where liability is imposed, a monetary or financial benefit to the defendant from the licensing arrangement is not a prerequisite to liability. *Taylor*, 537 F. Supp. 952 (E.D. Ky. 1982). Furthermore, all factors are not present in each case and the factors do not appear to be weighted equally. For example, cases involving a recognized trademark and the accompanying consumer expectations and reliance have uniformly imposed liability, while the trademark relationship alone has not been determinative. *Burkert*, 216 Conn. 65 (1990), *Kasel*, 24 Cal. App. 3d 711 (1972). *Torres*, 901 F.2d 750 (9th Cir. 1990). *Carter*, 360 F. Supp. 1103 (E.D. Pa. 1973). These cases may also be classified by the focus of the court's inquiry on participation or control by the defendant. Courts focusing on participation in the stream of commerce consistently imposed liability. *Kasel*, 24 Cal. App. 3d 711 (1972). *Fortman*, 211 Cal. App. 3d 241 (1989). *Taylor*, 537 F. Supp. 952 (E.D. Ky. 1982). *Connelly*, 75 Ill. 2d 393 (1979). Courts looking for control both have imposed liability, *Torres*, 901 F.2d 750 (9th Cir. 1990), and have exonerated the defendant, *Dillard*, 782 P.2d 1191 (1989).

UNIVERSITY LICENSING

Under the Dole-Bayh Act[9] universities have been granted the right to retain title to and to license federally-financed inventions, which covers a very large percentage of all university technology licensing. This Act was adopted in the hope that universities could establish licensing programs that would both benefit domestic industry by facilitating the commercialization of advanced technology created through government-sponsored research and generate royalty income to support further research by the university.[10] Small business firms are viewed as most successful at developing new products and creating employment; therefore, this right to retain title was coupled with a requirement that the universities and other nonprofit organizations give preference to small businesses as licensees.[11]

The combination of the preference for small business licensees and the current unclear state of product liability law[12] places the university in a difficult, uncomfortable, and untenable position when it attempts to license an invention in compliance with the mandate in the amendments to the Dole-Bayh Act and the rules adopted thereunder[13] without exposing the university to liability as a deep pocket. The likelihood of the imposition of strict liability on the university is unclear under the present law, and as small businesses often lack the financial resources to secure an indemnification agreement or to obtain product liability insurance, universities have been reluctant to license inventions to them.[14] As a result, product development has been slowed and U.S. competitiveness impaired.[15]

The university must endeavor to determine its exposure by applying the factors and tests from the case law as discussed above. Unfortunately the typical university licensing arrangement incorporates relationships and factors that cut both for and against liability. For example, all of the following characteristics, which are analogous to university licensing, have been used to support a finding of liability in the case law: (1) the licensing royalties received by the licensor; (2) the initial investigation and continual monitoring of the licensee by the licensor;[16] (3) the probable overlapping

personnel between the licensor and the licensee;[17] (4) the possibility of a long-term relationship between the licensor and the licensee; (5) any advice from or consultation with licensor personnel by the licensee; (6) the view that the licensor's invention is an indispensable part of the overall enterprise bringing a product to market. On the other hand, other characteristics of university licensing weigh against liability: (1) the intervening acts of the licensee; (2) the absence of consumer expectation or reliance on a licensor (university) name or trademark; (3) the lack of control on the part of the university;[18] (4) the socially desirable nature of technology transfer and the beneficial products that result from this activity.[19]

Likewise, the public policy arguments that have been made could both support and oppose the imposition of strict liability on a university licensor. For example, the fact that the university could serve as an additional source of risk and loss spreading, and the ability of the university to deter commercialization of hazardous inventions support strict liability. But on the other hand, strict liability would have a chilling effect on the vital transfer of technology from universities to their commercial licensees. Such transfer of basic technology has resulted in commercial development of socially desirable products, not likely to have been otherwise developed in the more applications-oriented industrial environment. Furthermore, academic freedom and American industrial competitiveness could be compromised through the inhibition of research and subsequent development.[20]

A LEGISLATIVE SOLUTION

The product liability uncertainties and risks that impede university licensing result from the clash of two public policies -- the policy of protecting consumers against product defects and the policy of advancing national competitiveness through the commercialization of university research. Courts may be ill-equipped to resolve this conflict in the timely and comprehensive manner required for university technology managers to obtain a reasonable level of comfort, particularly in dealing with small companies. This is a classic case for

legislative intervention. To be effective, such legislation needs to establish uniform national standards of liability.[21]

The most recently proposed federal product liability reform legislation does not address the issue of standards for licensor liability.[22] Although revision of this bill is one possible approach, it does not seem particularly promising as the bill deals with a multitude of other issues and has been pending in various forms for several years. Another alternative that could be of immediate benefit to universities is an amendment of the Dole-Bayh Act.[23] Such an amendment could limit university liability to the traditional negligence standard and could clarify that standard by specifying those limited circumstances in which it is reasonable to require universities to provide warnings or instructions regarding product dangers.[24] Universities can be protected in this regard by a "checklist" procedure at the time the technology is transferred to a commercial licensee.

It seems inevitable, in the years ahead, that legislators as well as technology managers must come to grips with the paralyzing effects of product liability exposure.

NOTES

1. Previous discussions are found in Swartz, *Licensing and Products Liability*, 20 Les Nouvelles, J. Licensing Executive Soc'y 41 (1985); Goldman, *Strict Liability and Intellectual Property Licensors - Keeping Closed a Can of Worms*, 66 J. Pat. Off. Soc'y 630 (1984); Cowan, *Tort Liability of Patentee Licensors*, 64 J. Pat. Off. Soc'y 87 (1982); Scola, *Licensor Liability in U.S.*, 15 Les Nouvelles, J. Licensing Executive Soc'y 166 (1980).

2. P.L. 96-517, 94 Stat. 3015 (1980).

3. The first contract was a trademark license that gave the defendant the right to inspect and control the product on which its trademark was used. The second agreement was a contract for sale of technical information whereby the defendant sold the manufacturer information about the scientific process relating to the production of ammunition. The third agreement was a technical services contract under which the defendant agreed to train and provide personnel for the manufacturer (licensee).

4. *E.g.*, *McClaflin v. Bayshore Equipment Rental Co.*, 274 Cal. App. 2d 446 (1969) (lessor); *Garcia v. Halsett*, 3 Cal. App. 3d 319 (1970) (licensee); *Vandermark v. Ford Motor Co.*, 61 Cal. 2d 256 (1964) (retailer).

5. "A licensor is an integral part of the marketing enterprise, and its participation in the profits reaped by placing a defective product in the stream of commerce presents the same public policy reasons for the applicability of strict liability which supported the imposition of such liability on wholesalers, retailers and lessors." 24 Cal. App. 3d 724.

6. Although not mentioned in the opinion, the situation in *Taylor* was similar to the market share cases involving DES. The court could have reasoned that since GM sold

99% of the blades, it should be held liable. This could explain the slant of the opinion and the outcome.

7. The actual source of the blade was unknown. It could have been a GM or Checker Cab part.

8. Atlantic was supplying fluid that was in reality dyed base oil.

9. P.L. 96-517, *supra* note 2.

10. H.R. Rep. No. 1307, 96th Cong., 2d Sess. 2 (1980).

11. This preference was added in the amendments to the Dole-Bayh Act found in P.L. 98-620, 98 Stat. 3335, 3366 (1984), 35 U.S.C. § 202(c)(7).

12. The development of product liability law and the doctrine of strict liability, as evidenced by case law, indicates that the current trend is to expand liability both up and down the chain of production and distribution. See *supra* note 5.

13. 37 C.F.R. § 401.7 (1990).

14. Statement of Robert Mosbacher, Secretary of Commerce, Before the Consumer Subcommittee of the Senate Committee on Commerce, Science and Transportation, (Apr. 5, 1990) *cited in* S. Rep. No. 356, 101st Cong., 2d Sess. 10, at note 50 (1990). *See also* Testimony of John Preston, Director of Technology Licensing at MIT, and Niels Reimers, Director of Technology Licensing at Stanford, Hearings on Product Liability Law Reform Before the Consumer Subcommittee of the Senate Committee on Commerce, Science and Transportation, (May 20, 1986) (Legal advisors now are recommending that universities not license any U.S. firm which has limited assets or is unable to provide adequate product liability insurance. Yet, it is exactly these small companies that have been

most effective in contributing to technology transfer and job creation.)

15. Statement of Robert Mosbacher, *supra* note 14.

16. Universities (and other non-profit agencies) performing federally-funded research agree to submit periodic reports on the utilization of the results of this research by the university or its licensees. 37 C.F.R. § 401.14(h) (1990). Indeed, failure to carefully select and monitor licensees may result in licensor liability under the traditional negligence theory. *Cf. Hixon v. Sherwin-Williams Co.*, 671 F.2d 1005 (7th Cir. 1982) (principal liable for failure to select a competent contractor).

17. University professors and researchers often possess expertise requested or required as part of the license by the company attempting to commercialize the technology. This type of overlap was present and noted by the court in *Kasel.*

18. The University and the federal agency that sponsored the original research retain "march in" rights to help ensure the development of inventions but lack any substantive control over the decisions made during the commercialization by the licensee. These rights allow the university to grant another license to a different user. The federal agency may require this if the original licensee is not effectively achieving practical application of the research. 37 C.F.R. § 401.14(j) (1990).

19. Special products, such as prescription drugs, are subject to different standards based on their social utility. In *Brown v Superior Court*, 44 Cal. 3d 1049, 245 Cal. Rptr. 412 (1988), the court distinguished prescription drugs from other products in determining the appropriate standards of liability in accord with Restatement of Torts, § 402A, comment k. The public interest in providing incentive to develop technologically advanced products with possible unknown risks on an affordable

basis warrants the use of the negligence-based, rather than strict liability, standard.

20. S. Rep. 356, *supra* note 14, at 10.

21. See S. Rep. 356, *supra* note 14, at note 95 for a discussion of the constitutional basis for Congressional legislation that preempts state liability laws.

22. S. 1400 reprinted in S. Rep. 356, *supra* note 14.

23. P.L. 96-517, *supra* note 2.

24. A bill containing such provisions is presented in Rosenblum, *Product Liability Risks of University Technology Licensing*, paper presented to Association of University Technology Managers, 1991 Annual Meeting, published in The Delphian, J. Risk Mgmt. for Higher Educ. Vol. I, No. 5. (Tillinghast Publications).

The Treatment of Tangible Personal Property in Conjunction with Licensing of Patented Biotechnology

Walter N. Kirn*

Biotechnology is said to be unique, and thus to create special problems in the field of intellectual property licensing. Karny, Biotechnology Licensing, 8 *Licensing Law and Business Report*, Clark Boardman Co. Ltd. (1985.) As to the premise - uniqueness of biotechnology - it is observed that living organisms, unlike machines, reproduce themselves. This statement suggests some sort of spontaneous creation free from man's intervention. This is not so. Replication of cells, for example, requires placing the cells in an appropriate environment that will supply them with nutrients essential for growth. In that light, living organisms are not much different, if at all, from certain other embodiments of intellectual property such as computer programs. See, for example, *SAS Institute, Inc. v. S&H Computer Systems, Inc.* 504 F. Supp. 816 225 U.S.P.Q. 916 (M.D. Tenn. 1985). If anything, the reproduction of a computer program is even easier than reproduction of a living organism.

The dichotomy between animate and inanimate tangible personal property does not justify drawing a distinction between the licensing of biotechnology and the licensing of other forms of technology. Any transfer of tangible personal

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*Walter N. Kirn is Associate Chief, Intellectual Property Counsel, 3M Company, St. Paul, MN 55133

property that enables the licensee to produce embodiments of the invention requires imposition of contractual obligations to assure that the licensor's expectations are realized and not subverted. Nevertheless, it cannot be doubted that biotechnology licensing involves consideration of tangible personal property matters to a greater extent than does other technology licensing. This is because of the present inability adequately to describe an invention in words and to reproduce readily that invention from the description using generally available materials.

Biotechnology licensing, like any other technology licensing, requires an accommodation to the needs of the parties. The licensee requires the transfer of sufficient tangible and intangible property to achieve the basic goal of practicing the claimed invention, usually for commercial purposes. On the other hand, the licensor desires to confine the property transfer to that calculated to result in the licensee's meeting its contractual obligations and, failing so, to permit effective recovery of that property -- both tangible and intangible. Achievement of these respective goals demands that the rights and duties regarding both forms of property be fully addressed in the written agreement(s) memorializing the intentions of the parties.

In the context of biotechnology licensor sees his being the only source of the raw material as a means of exercising the control the licensor desires. The supposed detriment of transferring a turn-key mini-factory to the licensee becomes a benefit, to the extent the licensor recognizes that the transfer affords an opportunity to exercise control over the licensee not necessarily available for conventional technology. To transform this from detriment to benefit requires designing the agreement to optimize control without shackling the licensee in its legitimate pursuits.

THE SALE OF BIOLOGICAL MATERIAL OFFERS LITTLE OPPORTUNITY FOR CONTINUING CONTROL

Of the available forms of tangible personal property transfer - outright sale, conditional sale, or bailment - bailment is the form that affords the licensor the most control over the property relative to the licensee and third parties.

An outright sale, *i.e.*, a transaction in which the tangible personal property is exchanged for an agreed-upon full purchase price paid upon transfer of the property, provides little if any opportunity for continuing control over the property by the licensor. Contractual prohibition against resale of biological material may be struck down as an improper restraint upon alienation. While restraints on alienation are not absolutely null and void, they are universally disfavored, and will be voided absent a showing that the restraint is a reasonable means of accomplishing a proper purpose. Even in the context of biotechnology licensing, there is a high risk that a court will disregard such a provision. More important, outright sale offers no possibility of controlling any progeny made from the supply of biological material sold by the licensor.

A conditional sale is a transaction in which title is reserved in the seller until the buyer satisfies specified conditions, whereupon title passes. This form of transfer also has disadvantages where the licensor desires to retain maximum control over the biological material. Any purported retention of title until the purchase price is paid creates a security interest by operation of U.C.C. § 2-401(1) (1972). The transaction is also governed by Article 9 of the U.C.C. The "conditional seller" must obtain a signed security agreement from the debtor and otherwise comply with U.C.C. § 9-203 to be able to enforce the interest even against the debtor, and in addition must perfect the security interest by filing a financial statement under U.C.C. § 9-307 or lose to all third parties who take priority over an unperfected security interest. These third parties include purchasers from

the "conditional buyer," certain lien creditors, trustees in bankruptcy, and others.

Another potential problem for the intellectual property holder who sells tangible personal property concerns the doctrine of implied license. If the only use of that tangible personal property is to practice a patented invention, the seller may be deemed to have granted the buyer a license to practice the intellectual property. *Adams v. Burke*, 84 U.S. (17 Wall) 453 (1873). It is doubtful that this doctrine presents much of a threat in the case of the sale of a material that must be combined with other materials in the process of manufacture of a new commodity. See, *Rubber Tire Wheel Co. v. Goodyear Tire and Rubber Co.*, 232 U.S. 413 (1914). Even if selling a given quantity of a biological material might carry with it an implied license to use that given quantity to produce a product, such as a protein by a patented method, it would not impliedly extend to a general license to produce progeny of the biological material for use in the patented method in the absence of a manifest intention to create such a license. *Rubber Tire Wheel Co. v. Goodyear Tire and Rubber Co.*, supra; *General Tire and Rubber Co. v. Firestone Tire Co.*, 349 F. Supp. 333, 174 U.S.P.Q. 427 (N.D. Ohio 1972).

Sales transactions are also directly subject to the warranty provisions of the U.C.C. Avoidance of the various U.C.C. implied warranties requires strict adherence to code requirements for disclaimers.

BAILMENT IS THE PREFERRED FORM OF TRANSFER OF BIOLOGICAL MATERIAL

Bailment seems uniquely suited to the licensor's exercise of continuing control over biological material and its progeny, while permitting the licensee to practice the patented technology. The primary feature of a bailment is the transfer of possession (but not title) to personal property to another for a purpose, with disposition of the personal property in accordance with the transferor's instructions after the purpose is accomplished. A true bailment relationship is not covered by Article 9 (Secured Transactions) of the U.C.C., and thus

the bailor is not required to comply with either § 9-203 or § 9-307 in order to prevail against secured creditors of the bailee. *In Re Sitkin Smelting & Refining, Inc.*, 639 F.2d 1213 (5th Cir. 1981); see also *Sandack v. Tamme*, 182 F.2d 759 (10th Cir. 1950). Hence, a bailment does not present the bailor with the vulnerability to third parties that a conditional sale presents. It takes no imagination to understand why a third party who stands to prevail against the unperfected security interest of a conditional seller would challenge an agreement that purports to be a bailment if there is any doubt as to its status as a bailment versus an unperfected security interest. The U.C.C. Article 2 warranties are also not directly applicable to bailments. Many jurisdictions, however, do apply the U.C.C. Article 2 warranty provisions to bailments by analogy. 48 A.L.R. 3d 668 (1973). The prudent licensor/ putative bailor will draft the bailment contract as if the U.C.C. warranties (U.C.C. §§ 2-312, 313, 314, and 315) are applicable, and consider as well the warranty disclaimer provision (U.C.C. § 2-316) and the provision extending express and implied warranties to third party beneficiaries (U.C.C. § 2-318).

In summary, bailment, rather than sale of biological materials in conjunction with an intellectual property license is favored if the licensor desires to maintain the maximum control over the material vis-a-vis the licensee and third parties. An outright sale offers virtually no opportunity for control over the initially transferred biological material and none over progeny. A conditional sale is preferable to an outright sale, but once the conditions of sale are met further control is lost. Conditional sales require compliance with Article 9 of the U.C.C. to protect the unpaid seller against third-party creditors of the buyer.

BAILMENTS - GENERAL PRINCIPLES

Black's Law Dictionary, 129 (4th ed., 1979) defines a bailment as:

> A delivery of goods or personal property by one person to another, in trust for the execution of a

> special object upon or in relation to such goods, beneficial either to the bailor or bailee or both, and upon a contract, express or implied, to perform the trust and carry out such object, and thereupon either to redeliver the goods to the bailor or otherwise dispose of the same in conformity with the purpose of the trust.

Important elements of the bailment are delivery of personal property to accomplish some object or purpose, retention of title by the deliveror, possession (combination of physical control and intent to exercise that control) by the deliveree, and disposition of the personal property by the deliveree in accordance with the deliveror's instructions. Early common law recognized six categories of bailments. Modern authorities recognize three categories - (1) for the sole benefit of the bailor; (2) for the sole benefit of the bailee; and (3) for the mutual benefit of both, 8 Am. Jur. 2d, Bailments §§ 16, 17. The bailment of biological materials in conjunction with a patent license would normally involve the third category.

To the extent not contrary to public policy, the rights and duties of the bailee with respect to the bailed property may be defined by contract. R. Brown *The Law of Personal Property*, § 11.5 (3d ed. 1975). In the absence of controlling contractual undertakings, the bailee in a bailment for mutual benefit is required to use ordinary care in protecting bailed property. Brown, *supra*, at 258. There are numerous other rights and duties which the common law imposes upon parties to a bailment relationship. It would be extremely unwise to leave the determination of the rights and duties of the parties to common law jurisprudence. The bailment contract should not only create the bailment but should define the respective rights and duties of the parties with respect to the bailed subject matter, each other, and to the extent possible, third parties. There are two principal issues with respect to creation of a biotechnology bailment; first, whether biological material that is continuously replaced by progeny, the original material eventually being lost, can be the subject of a bailment as a matter of law; and, second, whether in

substance the contract in its entirety evidences an intention to create a bailment in the subject property or merely creates a security interest by reservation of title for the purpose of assuring payment or performance of an obligation.

BIOLOGICAL MATERIAL - PARENT AND PROGENY - CAN BE THE SUBJECT OF A BAILMENT

In general, any personal property can be the subject of a bailment. However, in the context of a licensing arrangement wherein the original material transferred will be used as a starter for producing progeny, with the original material consumed or its identity lost, there is a threshold issue as to whether a bailment relationship can arise. Controversy existed at early common law whether a bailment may exist if the contract contemplated other than return of the property *in specie*. 8 Am. Jur. 2d, *Bailments* § 3. The law has resolved that narrow issue in finding a bailment where the property was converted to another form that was to be returned to the original deliveror (owner of milk delivers it to a factory to be made into butter or cheese, *First Nat. Bank v. Schween*, 127 Ill. App. 573, 20 N.E. 681 (1889). This principal was said to have been pushed to the extreme in *D. M. Ferry & Co. v. Forquer*, 61 Mont. 336, 202 P.193, 29 A.L.P.R. 642 (1921); Brown, *supra*, § 10.5. The contract provided that D. M. Ferry would provide seed to defendant farmer to plant, cultivate, harvest, and deliver the resultant seed crop to D. M. Ferry. D. M. Ferry had the right to reject unsatisfactory seed crop. The price paid to the farmer was a designated price per pound for seed crop accepted by D. M. Ferry. The contract specified that "the stock seed and seed crop produced from it is and shall remain" the property of D. M. Ferry. The Court, in holding that a bailment had been formed, likened the transaction to those where milk is delivered to make cheese, logs are delivered to make lumber, and the like. Accord: The *Rudy-Patrick Co. v. Dela Costa Farming Co.*, 16 Wash. App. 911, 557 P.2d 869 (Wash. App. 1977).

Another line of cases dealing with subject matter somewhat analogous to biological material is that involving

increase in bailed livestock. The general rule is said to be that increase during the term of a bailment belong to the bailee, but that the general rule is overridden by a specific agreement that increase goes to the bailor. 4 Am. Jur. 2d, *Animals* § 11.

The seed/crop and animal increase lines of cases are distinguishable from transactions involving personal property intended for consumption by the transferee. In these transactions, termed a *mutuum* from Roman or continental law, the subject matter transferred is to be consumed by the transferee (*mutuary*), and goods of like kind are to be returned to the transferor. A *mutuum* is said to be more akin to a sale and is treated as such. 8 Am. Jur. 2d, *Bailments*, § 48; *Brown On Personal Property*, p. 233, 3rd Ed. In the leading case, *New Domain Oil & Gas Co. v. Hayes*, 202 Ky. 377, 259 S.W. 715, 38 A.L.R. 172 (1924), a loan of drilling equipment was made in which the borrower was obliged to replace worn out and consumed equipment and to return the equipment in kind upon completion of work. The Court held the transaction to be a *mutuum*, to be accorded treatment akin to a sale rather than a bailment.

The result in *New Domain Oil* is to be compared with *Federal System of Bakeries v. Miller*, 92 W. Va. 442, 114 S.E. 749 (1922). A patentee of a baking system granted an exclusive license to use the system, as well as ovens and other appliances incorporating the patented invention. The agreement provided that all the equipment was to remain the sole property of the licensor. The licensee was required to replace broken or worn-out parts with parts purchased from the licensor. All renewed, replaced, and repair parts were to be the property of licensor. The transaction as to the equipment was held to be a bailment rather than a conditional sale, as there was no agreement that, upon certain contingencies, title to the equipment should pass to the licensee. Accordingly, the licensor was not required to record the licensing contract to protect its interest in the equipment against creditors of the licensee.

Biological materials such as plasmids and cells and their progeny are certainly akin to the stock seed and seed crop involved in *D. M. Ferry, supra*, and should be regarded as

appropriate subjects for bailments. The progeny is directly traceable to the licensor's parent material and is not merely material in kind, which characterizes a *mutuum*.

CREATION OF A BAILMENT RATHER THAN A SECURITY INTEREST

Bailments and conditional sales (termed a security interest under the U.C.C.) are similar, in that title to the personalty is reserved by the transferor, and custody and use are enjoyed by the transferee. Given the different treatment of bailments versus conditional sales under the U.C.C., particularly Articles 2 and 9, and the superficial similarities between the two transactions, it is not surprising that the question of lease or bailment versus security interest "is one of the most frequently litigated issues under the entire Uniform Commercial Code." J. White & R. Summers, Uniform Commercial Code, (2d ed. 1980). U.C.C. § 1-201(37) defines a "security interest" as follows:

> "'Security interest' means an interest in personal property or fixtures which secures payment or performance of an obligation. The retention or reservation of title by a seller of goods notwithstanding shipment or delivery to the buyer (Section 2-401) is limited in effect to a reservation of a 'security interest'.
>
> "Whether a lease is intended as security is to be determined by the facts of each case; however, (a) the inclusion of an option to purchase does not of itself make the lease one intended for security, and (b) an agreement that upon compliance with the terms of the lease the lessee shall become or has the option to become the owner of the property for no additional consideration or for a nominal consideration does make the lease one intended for security."

If the parties intend a true bailment, provision (b) of U.C.C. § 1-201(37) must be avoided.

In re Alpha Creamery Co., Inc., 4 U.C.C. Rep. Serv. 794 (W.D. Mich. 1967) set forth helpful guidelines for determining whether or not an agreement is a security agreement:

"1. The facts in each case control to show intention of the parties to create a security interest.
2. Reservation of title in a lease or option to purchase appurtenant to or included in the lease does not in and of itself make the lease a security agreement.
3. Lease agreement which permits the lessee to become the owner at the end of the term of the lease for a nominal or for no additional consideration is deemed intended as a security agreement as a matter of law.
4. The percentage that option purchase price bears to the list price, especially if it is less than 25%, is to be considered as showing the intent of the parties to make a lease as security.
5. Where the terms of the lease and option to purchase are such that the only sensible course for the lessee at the end of the lease term is to exercise the option and become the owner of the goods, the lease was intended to create a security interest.
6. The character of a transaction as a true lease is indicated by:
   (a) Provision specifying purchase option price which is approximately the market value at the time of the exercise of the option.
   (b) Rental charges indicating an intention to compensate lessor for loss of value over the term of the lease due to aging, wear and obsolescence.
   (c) Rentals which are not excessive and option purchase price which is not too low.
   (d) Facts showing that the lessee is acquiring no equity in leased article during the term of the lease."

Observance of the *Alpha Creamery* guidelines should enable the parties to end up with an agreement that meets the expectations of the parties *inter se* and the parties as to third parties.

SPECIFIC PROVISIONS OF THE BAILMENT CONTRACT

The vagaries of common law treatment of bailments and the potential for third-party attack mandate that the rights and duties of the parties with respect to the bailed property be specifically and thoroughly addressed in a written agreement. Some of the more important topics to be addressed in the agreement are discussed below.

A. Separate Intellectual Property and Bailment Agreements

If for no other reason than to minimize confusion between the intellectual property and the tangible personal property, it would be advisable to have separate agreements for each type of property with appropriate cross-referencing where necessary.

B. Specific, Unambiguous Definitions of Bailed Property - Parent and Progeny

The bailment agreement should define the bailed property specifically and unambiguously. Both transferred biological material and derivations thereof should be included in the definition of the bailed goods. Any confusion in the description could defeat the bailment altogether and will certainly lead to difficulties in gaining return of all the biological material including progeny.

C. Title Remains In Bailor - Possession In Bailee

In keeping with the fundamental nature of a bailment, the agreement must expressly reserve title in the bailor. If the bailee is to be given an option to purchase, the option price must be more than nominal. The agreement must also provide for delivery of the bailed property to the bailee and

the right of the bailee to possess such property, including progeny, throughout the term of the bailment.

D. Prohibition Against Commingling

The bailor is advised to prohibit the bailee from commingling the bailed property with other biological material, except, of course, for nutrients and other material incidental to practicing the licensed invention. Commingling has been considered a conversion of the bailed property. See In re Bristol Indus. Corp., 38 U.C.C. Rep. Serv. 989 (D.C. Conn.) (1981), rev'd on procedural grounds 690 F. 2d 26, 34 F.R. Serv. Id. 1076 (2d Cir. 1982); but see concurring opinion, 38 U.C.C. Rep. Serv. at 1007.

E. Provision for Labelling and Security

Labelling the storage containers for the biological material as property owned by the bailor further evidences the intention to create a bailment. It would also be prudent to specify the facility where the bailed property is to be kept during the bailment, allowing movement only to other facilities that are owned or controlled by the bailee after the bailor's written approval. Movement from one state to another should alert the licensor/bailor to file a precautionary financing statement in the new state pursuant to U.C.C. § 9-408, as discussed infra. Confining the location of the approved facilities to those within covered by the licensor's patents would appear to be a wise and legal precaution.

The bailor should also require the bailee to maintain adequate security to prevent theft, loss, or destruction of the bailed property. The parties should specify the degree of care the bailee is required to exercise to avoid such loss. Of course, voluntary transfer of bailed property by the bailee should be prohibited. The contract should enable transfer of the biological material if required by legal authority, with appropriate precautions to preserve confidentiality and prevent unlicensed use.

F. Use of The Biological Material

The agreement should specify precisely what the bailee is permitted to do with the bailed property, as well as what the

bailee is not permitted to do. The permitted use must be at least as broad as the rights granted under the intellectual property license but preferably no broader. At common law, any use of bailed property by the bailee for his purpose in a manner inconsistent with and in defiance of the bailor's rights is a conversion. *Tessmar v. Grosner*, 23 NJ 193, 128 A 2d 467 (1957). To avoid misunderstandings, any use the bailor desires to prohibit should be specified with particularity in the bailment agreement. In the context of biological materials, if the bailor is concerned about the bailee isolating a gene, and using that gene in conjunction with other materials to avoid infringement, the bailment agreement should prohibit such use. While a use of the biological material by the licensee may be beyond the scope of the intellectual property license yet technically within the patent grant, the use may not be an infringement if done for experimental purposes. Consequently, unlicensed patent rights will not afford a remedy for the bailor/licensor and in any event, it would normally be preferable to sue on the bailment contract rather than on the patent.

G. Compensation For Use of Biological Material

There are a number of factors to consider in setting any price for possession and use of the biological material that is the subject of bailment. Generally, there will not be an ascertainable market price for the material. This affords the licensor some flexibility in charging a use fee (apart from any intellectual property license fee) because the licensor does not have a fixed ceiling under which to charge in order to avoid a sale interpretation. Nevertheless, the licensee will accept an overall charge of only so much, regardless of whether it is earmarked for the tangible or intangible property.

Allocating too much to the use fee diminishes the apparent value of the intellectual property. This may have several adverse results, including substantially reducing the measure of damages a court might award the licensor for infringement of the licensed patent. Allocating nothing or a nominal amount of the licensor's compensation to the possession and use of the biological material poses no particular legal problem, at least prior to expiration of the

licensed patent. However, the licensor would run great risk of violating the prohibition against post-expiration royalties if the fee earmarked as the tangible property use fee during the patent license was increased after expiration of the licensed patent. *Brulotte v. Thys*, 379 U.S. 29 (1964). With that proviso, there is no prohibition against requiring payment of a reasonable use fee for continued use of the biological material after expiration of the licensed patent. It would seem advisable, however, to permit the user (former licensee) to cancel the bailment at will after expiration of the licensed patent to avoid any claim that the obligation to possess, use, and pay for the bailed biological material was forced upon the licensee/bailee by leveraging the patent rights.

H. Warranties and Disclaimers

A distinction is drawn between bailment of a particular chattel and bailment of a chattel for a particular use. As a general rule, the implied warranty of fitness for the intended use is implied only in the latter case. 8 Am. Jur. 2d, *Bailments* § 158. In most instances, the bailment of biological material for use in practicing an invention will be of the latter variety.

The implied warranty of fitness should be addressed. As noted above, some jurisdictions apply Article 2 U.C.C. warranties to bailments by analogy. In those jurisdictions, it would be good practice to adhere to the U.C.C. disclaimer provisions as well. U.C.C. § 2-316 requires that exclusion of the implied warranty of fitness be in writing and conspicuous. The implied warranty of fitness is also negated to the extent the bailee examines the goods before entering into the contract or is given the opportunity but refuses upon demand to examine the goods. Any defects that examination ought to have revealed are negated. U.C.C. § 2-316(3)(b).

In the context of biotechnology licensing, the bailee expects the biological materials to be suitable for producing progeny and end product in at least minimum yields. It will often be feasible and advisable for the parties to agree upon a test for determining viability, productivity and other characteristics essential to achieving the intended results. Biological material that passes the test may be conclusively

presumed free from defect, and thereupon the implied warranty of fitness for a particular purpose is negated. The testing, if done prior to entering into the contract negates the implied warranty as to detectable defects without the need for a conspicuous written disclaimer. U.C.C. § 2-316. If the testing is done after the contract is entered into, a conspicuous written disclaimer is required. Such a disclaimer might read:

> UPON PASSAGE OF THE TEST OF EXHIBIT A, THE WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE SHALL BE CONCLUSIVELY AND FOREVER NEGATED AND DISCLAIMED AS TO ALL DEFECTS FOR ALL BIOLOGICAL MATERIAL TRANSFERRED TO THE BAILEE, ALL PROGENY THEREOF, AND ALL PRODUCTS MADE FROM THE TRANSFERRED BIOLOGICAL MATERIAL AND PROGENY.

The implied warranty of merchantability refers to fitness for the ordinary purposes for which the goods are used, as contrasted to the implied warranty of fitness for a particular purpose. Where the general use and the specific use are one and the same, as will generally be the case in the context of biotechnology licensing, there seems to be little advantage in distinguishing between a breach of the implied warranty of fitness for a particular purpose and the implied warranty of merchantability. Disclaimer of the implied warranty of merchantability requires mentioning "merchantability" and in the case of a writing must be conspicuous. U.C.C. § 2-316(2)

The warranties of title and against infringement must also be considered in the bailment contract, particularly in those jurisdictions where the U.C.C. warranties are applied to bailments by analogy. The bailee/licensee should insist upon a warranty of title including a warranty that transfer is rightful and that the biological material is free from any security interest or other encumbrance of which the bailor had knowledge at the time of contracting. See U.C.C. § 2-312.

The U.C.C. also provides for a warranty that the goods are delivered free of the rightful claim of any third party by way of infringement or the like. To the extent this warranty is applied to a bailment, the bailor must be a merchant regularly dealing in goods of the kind bailed. The definition of merchant under the U.C.C. would seem broad enough to include the typical licensor of biotechnology. U.C.C. § 2-104. The bailment contract should address this warranty. The bailee should insist, at the minimum, that the bailor represent that he has no knowledge of any patents in relevant jurisdictions that would be infringed by the bailee's possession and use of the biological material or by the sale of products made from the biological material.

The bailment contract should also specify the extent of the bailor's undertaking in the event the bailee is sued for patent infringement, regardless of whether the infringement action would constitute a breach of the implied warranty against infringement.

Express warranties under the U.C.C. may be made by affirmation, promise, description or sample. Where the parties agree upon a test as the definitive determination that the biological material meets the needs of the licensee/bailee, is appropriate to state that no express warranties are made by the bailor.

I. Provision for Filing Financing Statement

Assuming an agreement relating to transfer, possession, and use of a biological material is a bailment, Article 9 of the U.C.C. is inapplicable. A claim to the bailed subject matter by a levying creditor or trustee in bankruptcy of the bailee will be defeated by the bailor. *White & Summers, supra.*

If the agreement is characterized as a conditional sale, however, the seller's security interest is subject to Article 9, and the seller is vulnerable to secured creditors unless the seller has perfected his security interest by filing a financing statement, U.C.C. § 9-302.

As a precaution against loss of the bailed goods to a third party secured creditor or trustee in bankruptcy, the putative bailor is advised to file a financing statement under U.C.C. § 9-408. Filing a statement constitutes perfection of the

security interest in the bailed goods in the event the agreement is construed as a conditional sale creating a security interest rather than a bailment. U.C.C. § 9-408. Filing a statement is not an admission that the contract creates a security interest rather than a bailment. Filing of a financing statement thus presents a "no lose" opportunity for the putative bailor.

The formalities of financing statements are governed by U.C.C. §§ 9-103, 401, 402 and 403. The financing statement as to contracts relating to possession and use of biological materials should be filed with the Secretary of State's office in the state where the materials will be kept. The financing statement is good for five years, renewable for successive five-year periods by filing a continuation statement within six months prior to expiration of any five year period.

J. Cancellation of the Bailment

The rights of either party to cancel the bailment agreement and the effect such a cancellation should have on the patent license agreement are matters requiring a great deal of thought. The licensor/bailor does not want to transfer the biological materials to the licensee/bailee to enable such party to practice the patented invention, and then have the patent license alone terminated. Granted, the licensor can sue for patent infringement, but the licensee will be in possession of the biological material and will have the ability, if not the right, to practice the invention until and unless the patent is declared valid, infringed, and enforceable. Accordingly, the bailor/licensor should generally insist that cancellation of the patent license either by the licensee for any reason or by the licensor for breach would give the licensor the right to cancel the bailment agreement and to have the biological materials returned.

Permitting cancellation of the bailment agreement by the licensee/bailee without concomitant cancellation of the license agreement does not pose the problem to the licensor that the reverse situation poses. If the bailed biological material is necessary to practice the licensed technology, and the licensor is the only source of the material, the return of the material to the bailor will deprive the licensee/bailee of the ability to

practice the technology. Assuming that the biological materials are covered by the licensed patent, they could not legally be obtained from any unlicensed source. If the biological materials are not claimed in the licensed patent and are staple items of commerce, prohibiting cancellation of the bailment agreement might well be regarded as an illegal tie-in. See, *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176 (1980). To avoid any possibility of an illegal tie-in, the bailment agreement could permit the licensee/bailee to cancel the bailment at any time with or without cause and without requiring cancellation of the license agreement. However, the law does not require the licensor to go that far, as an illegal tie-in is avoided if the biological material under bailment is either covered by claims of the unexpired licensed patent or is not a staple article or commodity of commerce suitable for substantial noninfringing use.

K. Liability to Third Parties, Insurance

The bailor's liability to third parties arising out of injuries relating to exposure to or use of the biological materials or products thereof is essentially the same as that of a seller. Possession and control of the biological materials resides in the bailee. Provided the bailed biological materials are fit for their intended purpose and/or the injury is not attributable to the defect rendering the materials unfit, the bailor is not liable for injuries to third parties. 8 Am. Jur. 2d, *Bailments* § 274.

The bailor-bailee relationship is not as such governed by the doctrine of respondeat superior applicable to master-servant and to principal-agent relationships. It is advisable to specify in the agreement that the licensee/bailee is not the agent of the licensor/bailor and shall refrain from expressly or impliedly representing itself as such.

Bailee liability will arise, however, if the bailor has been negligent in entrusting a dangerous article to a bailee unfamiliar with its dangerous quality, uninstructed in its use, or incompetent to use due care. See, *Restatement Torts* 2d §§ 338, 390, 405, 407. In the context of biotechnology licensing, the licensee would normally be considered to have such expertise and sophistication that this rule of liability

would rarely apply. Nevertheless, it behooves the bailor/licensor to fully apprise the bailee/licensee of any special dangers associated with the biological materials, as well as any precautionary measures that should be taken to avoid injury.

Despite the generally limited exposure of bailors to third party liability, the coupling of biotechnology and the ever-expanding reach of product liability make it advisable, if not imperative, to require that the bailee carry liability insurance naming both the bailor and bailee as insured. Annual review of the policy limits by both parties and adjustments to reflect changes having the potential for increased liability should be provided.

L. Expiration

The bailee/licensee should insist upon having the right to possess and use the bailed biological material for so long as it desires to remain in business after the licensed patent expires or after all claims of the licensed patent covering the licensee's activity are held invalid. Otherwise, the bailee faces the loss of substantial investment. The bailee should also have the right to terminate the bailment at any time after expiration of the licensed patent or determination of invalidity with or without cause. Any cancellation should activate the provision for return of the biological material to the bailor.

CONCLUSION

The licensing of biotechnology patent rights often requires concomitant transfer of biological materials to enable the licensee to practice the patent rights. To provide maximum control over the licensee's activity under the patent license as well as the licensee's use of the biological material, the licensor may consider it advisable to create a bailment of the biological material transferred, as well as all progeny thereof, and to specify in detail the rights and obligations of the bailee/licensee with respect to the material that is the subject of the bailment.

Note:

The thesis of this paper, first presented orally at the American Intellectual Property Law Mid-Winter meeting in 1986, is that licensing of biotechnology inventions often entails the transfer of biological materials, tangible personal property, in addition to patent or trade secret rights, intangible personal property. The licensing agreements at that time failed to adequately address the rights and duties of the parties vis-a-vis the biological materials per se, invoking instead terminology that was uniquely designed to deal with the intangible property rights being licensed. The author sought, first, to draw transfer of material, and second, to address the options available to effect the transfer. The traditional transactions -- absolute sale, conditional sale, and bailment -- were discussed, and the conclusion reached that the latter form of transaction gave the licensor/transferor maximum control over the licensee's use of the biological materials. The history of the law of bailments was also reviewed with the conclusion that this ancient form of tangible property transfer was legally, as well as functionally appropriate to biotechnology licensing. Subsequently the transfer of biological materials as a bailment has received widespread approval and use in the biotechnology community.

Animal Patenting

Joan V. McCormack*

I. INTRODUCTION

On April 12, 1988, the first United States patent granted on an animal was issued to Harvard University. (TRANSGENIC NON-HUMAN MAMMALS, U.S. Patent No. 4,736,866; Inventors: Philip Leder and Timothy A. Stewart). The subject matter of this patent was a transgenic mouse that was genetically engineered to contain a cancer-causing gene.

A transgenic animal is one that carries a "foreign" gene as part of the chromosomes of the germ line. In the Harvard patent, the "foreign" gene was described as being any one of a long list of viral and cellular oncogenes. Transgenic mice having these oncogenes presumably could then be used to test possible carcinogens.

The ability to express "foreign" genes in an animal, especially of a different species, gives rise to limitless possibilities of genetic manipulation. Such transgenic animals may have important medical and scientific uses, as well as agricultural and industrial applications. The creation of transgenic animals, however, has also raised a number of controversial social issues. A lawsuit was filed by animal rights groups challenging the authority of the Commissioner

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*Joan V. McCormack is Senior Licensing Associate, University of California, Office of Technology Transfer, Alameda, California, 94501.

of the U.S. Patent and Trademark Office to grant patents on animals. There have also been several unsuccessful attempts to pass legislation that would limit patent protection for transgenic animals.

Despite the controversy, scientists continue to work in this area and have succeeded in producing transgenic mice, rabbits, chickens, sheep, and pigs. Much of this research is being done at American universities. The Industrial Biotechnology Association estimates that there are currently between 70 to 100 U.S. patent applications pending for transgenic animals.

This paper will examine the various issues to consider in the patenting of transgenic animals.

II. OVERVIEW OF THE TECHNOLOGY AND ITS USES

Transgenic animals have been produced by several techniques: microinjection of foreign DNA into the pronucleus of fertilized eggs; infection of embryos with retroviruses carrying foreign DNA in the viral genome; and injection of genetically altered embryonic stem cells into embryos (Jaenisch, R., *Science* 240: 1468-1474, 1988).

The most commonly used technique for introduction of foreign DNA material has been by microinjection of the pronucleus of a fertilized egg. After injection, the eggs are then implanted into a female to develop into transgenic animals. This was the method that was described to produce transgenic mice in the Harvard patent, and is now considered a "routine procedure" in mice (Clark, A.J., *Bio/Technology* 7: 487-492, 1989). Microinjection in other species may be more difficult because of problems in visualizing the pronucleus of the fertilized egg (Hammer, Robert E., *et. al.*, *Nature* 315: 680-683, 1985).

The success rate in producing transgenic animals, however, is relatively low. For example, Robert E. Hammer, *et. al.*, successfully produced transgenic rabbits, sheep, and pigs by microinjection of the fusion gene MT-hGH (metallothionein/human growth hormone) (Hammer, Robert E., *et. al.*, *Nature* 315: 680-683, 1985). A total of about

5,000 fertilized eggs were injected and transferred to recipient females, resulting in 483 fetuses or neonates. Integration of the MT-hGH gene in these 483 animals occured in only 1.3% of the sheep; 10.4% of the pigs; and 12.8% of the rabbits. (Cf. the integration frequency of approximately 27% in earlier experiments with mice). These results are set forth, in part, below.

Table 1: Efficiency of producing MT-hGH transgenic rabbits, sheep and pigs by microinjection

Species	Transferred injected ova	Recipient females	Integration frequency
Rabbit	1,907	73	28/218 (12.8%)
Sheep	1,032	192	1/73 (1.3%)
Pig	2,035	64	20/192 (10.4%)

Hammer, Robert E., *et. al.*, *Nature* 315: 680-683, at p. 682 (1985). (EXCERPT).

Practical application of transgenic animal technology may depend on the type of use anticipated. There are roughly three different categories of projected uses for transgenic animals: 1) to further medical and scientific research; 2) to produce valuable proteins; and 3) to improve livestock.

The Harvard patent described several potential uses for its transgenic mouse invention in the area of medical and scientific research. These transgenic mice, which carry an oncogene, could be used to test possible carcinogens. This type of test system for potential carcinogens may be far superior to the existing "Ames test" (which measures mutagenicity of bacteria in response to application of the suspected substance) and animal studies performed at the maximum tolerated dose of the chemical tested (recently criticized by Ames, Bruce N., *et. al.*, *Science* 249: 970-971, 1990). The Harvard mouse could also be used to test substances that are thought to protect against the development

of cancer. Transgenic animals of the Harvard invention may further provide immortal cell lines for tissue types not otherwise available. Many other medical and scientific uses for transgenic animals can be imagined, such as models for human diseases and for studying gene expression.

Transgenic animals may also be used as "bioreactors" to produce proteins which could be targeted to the mammary gland and recovered from milk. Successful expression of valuable human proteins has already been demonstrated in the milk of transgenic rabbits (Buhler, Th. A., *et. al.*, *Bio/Technology* 8: 140-143, 1990) (human interleukin-2); sheep (Clark, A.J., *et. al.*, *Bio/Technology* 7: 487-492, 1989) (human anti-hemophilic factor IX); and mice (Gordon, K., *et. al.*, *Bio/Technology* 5: 1183-1187, 1987) (human tissue plasminogen activator). Practical use of proteins expressed in the milk or other body fluids of transgenic animals will involve overcoming certain regulatory concerns, but these concerns may be similar to the issues already addressed in the production and use of recombinant proteins.

More serious regulatory problems may be involved in the use of transgenic technology to alter the characteristics of livestock. Projected improvements for farm animals include increased feed efficiency, improved nutrient content, and disease resistance. These applications are perhaps the most controversial uses of transgenic technology, and are the focus of much of the protest by farmers, animal rights advocates, and other special interest groups. The production of transgenic livestock also appears to require a tremendous investment of time and money which may make this use of the technology unacceptable (Van Brunt, J., *Bio/Technology* 6: 1149-1154, 1988).

III. DEVELOPMENT OF THE LAW

There are three basic requirements for patentability under the United States patent laws: utility, novelty, and nonobviousness. Title 35, United States Code, Sections 101-103. Patentable subject matter is defined at section 101 as "any new and useful process, machine, manufacture, or

composition of matter, or any new and useful improvement thereof." The Supreme Court has ruled that neither the "laws of nature" nor "the handiwork of nature" are patentable subject matter. *Parker v. Flook*, 437 U.S. 584, 198 U.S.P.Q. 193 (1978); *Funk Seed Co. v. Kalo Co.*, 333 U.S. 127, 76 U.S.P.Q. 280 (1948).

In 1979, the Court of Customs and Patent Appeals held that a "biologically pure culture" of a newly discovered microorganism was patentable subject matter under section 101. *In re Bergy et. al.*, 596 F.2d 952, 201 U.S.P.Q. 352 (CCPA 1979). This new microorganism, *Streptomyces vellosus*, was capable of producing the antibiotic lincomycin under proper culture conditions. The U.S. Patent and Trademark Office (PTO) had already granted Bergy claims to the process of producing lincomycin from this microorganism, but a claim to a pure culture of the microorganism was rejected as a "product of nature" (and therefore non-statutory subject matter).

The Court in *Bergy* reasoned that if the functioning of a living organism could be patentable (as process claims), it would be "illogical" to exclude the "existence of life in a manufacture or composition of matter in the form of a biologically pure culture of a microorganism" as unpatentable subject matter. 201 U.S.P.Q. 352, at 375. The *Bergy* Court rejected the assertion that their decision would extend the patent laws, citing the patent claim granted to Louis Pasteur in 1873 for yeast "free from organic germs." See United States Patent No. 141,072. The *Bergy* holding was carefully limited to the claims at issue, and the Court clearly stated that it was "not dealing with all living things." 201 U.S.P.Q. 352, at 373.

In 1980, the Supreme Court addressed the question of whether genetically engineered bacteria could be patentable subject matter under section 101. *Diamond, Commissioner of Patents v. Chakrabarty*, 100 S. Ct. 2204, 206 U.S.P.Q. 193 (1980). The bacteria at issue in the claims were new strains of *Pseudomonas* which were created by the addition of plasmids capable of degrading four different components of oil. The Court found that the patentee had produced a "new

bacterium with markedly different characteristics from any found in nature," which were "not nature's handiwork, but his own;" and that these new strains of bacteria were, therefore, patentable subject matter. 206 U.S.P.Q. 193, at 197.

The PTO Board of Patent Appeals and Interferences interpreted the *Chakrabarty* case as authority for the broad proposition that patentable subject matter includes man-made life forms. *Ex parte Allen*, 2 U.S.P.Q. 2d 1425 (PTO Bd Pat App & Int 1987). *Allen* was an appeal from the PTO's rejection of claims to polyploid oysters. Claims to the method of producing polyploidy in oysters (to increase growth) had already been allowed. The *Allen* Court reversed the examiner's rejection of claims to the oysters, stating that the issue under section 101 was "simply whether that subject matter is made by man." 2 U.S.P.Q. 2d 1425, at 1426.

The *Allen* case was decided on April 3, 1987. Four days later, on April 7, 1987, the PTO issued a policy statement that non-human non-naturally occuring animals constituted patentable subject matter. Notice, "Animals-Patentability" 1077 OG 24. (Humans are excluded from patentability as a constitutional matter). This announcement recognized the effect of the *Allen* case which, as a decision of the Board of Patent Appeals and Interferences, is binding authority for the PTO. In other words, whether *Allen* correctly interpreted the Supreme Court holding in the *Chakrabarty* case is irrelevant to the PTO examiners because they must follow the decisions of the Board.

A year later the PTO issued the first United States patent to be granted on an animal to Harvard University for TRANSGENIC NON-HUMAN MAMMALS, U.S. Patent No. 4,736,866, Inventors: Philip Leder and Timothy A. Stewart. The subject matter of this patent was a transgenic mouse that was genetically engineered to contain a cancer-causing gene. The claims of this patent are not limited to mice, however, and include "A transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage." Claim 1, U.S. Patent No. 4,736,866.

The authority of the PTO Commissioner to grant patents on non-human non-naturally occuring animals was immediately challenged by a lawsuit filed in the Northern District of California. *Animal Legal Defense Fund v. Quigg*, Civil Action No. 88-2938 (N.D. Cal. 1989). This action charged that the Commissioner had improperly extended patent protection to animals, and alleged that the Notice issued in April, 1987 (*supra*) was improper. The suit was initially dismissed in favor of the Commissioner. The appeal to the Ninth Circuit Court of Appeals resulted in a decision on April 6, 1990, ordering the District Court to transfer the matter to the Court of Appeals for the Federal Circuit in Washington, D.C. because it raised a patent issue.

The Court of Appeals for the Federal Circuit held that the plaintiffs lacked standing to challenge the notice. *Animal Legal Defense Fund v. Quigg*, 18 U.S.P.Q. 2d 1677 (CAFC 1991).

Congressman Robert W. Kastenmeier (Wisc.) convened hearings on the subject of animal patenting in 1987. *Patents and the Constitution: Transgenic Animals, Hearings of the House of Representatives' Subcommittee on Courts, Civil Liberties, and the Administration of Justice, Committee of the Judiciary (1987)*. These hearings provided a forum for a wide variety of special-interest groups to voice their concerns about the technology. See discussion of "Controversial Issues", *infra*. Kastenmeier also sponsored the "Transgenic Animal Patent Reform Act", which would have exempted farmers from infringement in reproducing a transgenic farm animal. This bill was not enacted into law.

IV. CONTROVERSIAL ISSUES

The availability of patent protection for transgenic animals has raised a number of controversial issues. See Kastenmeier Hearings, *supra*. Groups opposing the development of transgenic animals have raised concerns about animal suffering, loss of genetic diversity, safety of food products; economic effect on the small farmer, ecological matters, and ethical/religious issues. Others argue that the

development of transgenic animals can provide significant scientific and medical advances; that many of the same objections can be raised about selective animal breeding; that development of transgenic farm animals may actually reduce costs to small farmers; and that the U.S. must maintain a competitive advantage in this developing technology.

It is clear that these controversial issues relate to the technology, rather than the patent system. The Supreme Court addressed similar concerns about the emerging biotechnology industry in its decision in the *Chakrabarty* case:

> We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life...It is argued that this Court should weigh these potential hazards in considering whether respondent's invention is patentable subject matter under section 101. We disagree. The grant or denial of patents on microorganisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occured when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more that Canute could command the tides. Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.

206 U.S.P.Q. 193, at 200 (1980).

The United States patent laws were enacted by Congress pursuant to constitutional authority: "To promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." United States Constitution, Article I, section 8, clause 8. In exchange for these exclusive rights, the inventor must fully disclose his or her invention so that the technology can be practiced upon expiration of the patent.

While Congress may have the authority to exclude multicellular animals from the definition of patentable subject matter under section 101, this may not affect significantly the progress of transgenic animal research. If patent protection is not available, those wishing to commercialize the technology will use alternative modes of protection. For example, the inventor may elect to protect his transgenic animal technology as a trade secret and license use of the animals under a personal property bailment agreement. This would allow the technology to be commercialized without any contribution to the advancement of scientific knowledge. Thus, an attack on the patent system by opponents to transgenic animal technology may be misplaced.

It is also important to note that several governmental agencies would have regulatory authority over the various uses of transgenic animal technology, such as the federal Recombinant DNA Advisory Committee, the United States Department of Agriculture, and the Environmental Protection Agency.

V. PRACTICAL CONSIDERATIONS

An applicant for a United States patent must provide a full disclosure of his or her invention which would "enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. section 112. Thus, a patent application for claims to a transgenic animal may require a deposit of biological material. In the case of the Harvard patent, plasmids bearing the fusion genes described in the

specification were deposited in the American Type Culture Collection (ATCC).

In certain cases, however, a deposit of germ cells or frozen embryos may be required. One university technology transfer office related that they declined to pursue patent protection on a transgenic animal invention because a deposit of frozen embryos would be required. While the ATCC indicated that it could maintain such a deposit, the university would be required to provide several hundred frozen embryos. Neither the inventor nor the university had the time and financial resources required to provide such a large amount of valuable biological material. Another university reports that it is facing an enablement and best mode rejection on a patent application for a transgenic mouse where a deposit of the plasmid DNA was made. The examiner has requested a deposit of the transgenic mice or their embryos.

In addition to the costs of obtaining patent protection, actual commercialization of transgenic animals may prove to be prohibitively expensive, particularly for larger animals (Van Brunt, J., *Bio/Technology* 6: 1149-1154, 1988). In livestock, for example, the time and expense required to create a more desirable animal may far exceed the economic value of the improvement.

Commercialization of university transgenic animal inventions could also be affected by the controversial issues raised by groups opposed to the technology. University technology managers will need to weigh those concerns on a case by case basis against the potential public benefit of particular transgenic animal inventions.

In any case, it appears that research in this area will continue and that new invention disclosures should be expected.

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