BOS GLOBE, 12/30/2005

He supplies ammunition to fight commercialization of science

By Carol Cruzan Morton
GLOBE CORRESPONDENT

For 20 years, Sheldon Krimsky has been sounding the alarm about how corporate interests may corrupt the academic mission.

Science, especially, is supposed to be the source of open, free, and unbiased information. But Krimsky has collected enough evidence and anecdotes to fill a new book about science conducted by researchers who stand to profit from their work or whose research is funded by companies with even more at stake. The commercialization of university science will eventually deplete research conducted for the public good, such as identifying toxic dangers or environmental causes of disease, he argues in "Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?"

"The question I always get asked is, what difference does it make if the researchers are following the canons of good science?" Krimsky said.

The answer, Krimsky said, is that research funded by industry tends to be more pro-business than research funded by universities and government.

"This is a statistical result, it doesn't mean that every scientist who is sponsored by industry is going to produce results that are necessarily in favor of the industry's financial interest," he said. "But if you compare the industry-funded studies with non-profit and government funded ones, you get a skewing of the research toward proindustry conclusions."

The classic example: Studies done for tobacco companies that consistently find fewer health problems from smoking than studies funded by those without a financial interest in the outcome.

"It's true in the alcohol industry as well," Krimsky said. And the toy industry, he added, funds "studies which show that there's no relationship between toys and violent video games and children's behavior."

The Tufts University professor is certainly not the only person to take on possible conflicts in the scientific world, but his scholarship provides the data that many advocates use in making their case.

Even defenders of the commercial ties, who say they speed products to the market and appropriately reward researchers for their work, recognize the importance of Krimsky's data.

"He has been a voice of caution for decades," said Lita Nelsen, director of the technology licensing office at Massachusetts Institute of Technology. "Whether you agree or not, he makes you think. We take it seriously and manage [potential conflicts] with very strict conflict of interest rules. We don't have to give away our souls if we want discoveries to move from the library shelf to medicine bottles."



Tufts professor Sheldon Krimsky has written a book about science conducted by researchers who stand to profit from their work or whose research is funded by industry.

Sheldon Krimsky

Born: Brooklyn, N.Y.
Home: Cambridge
Education: Master's degree in physics from Purdue University, master's and doctorate in philosophy from Boston University
Least favorite subject in elementary school: Biology (too much to memorize)
Subject of first book: "Genetic Alchemy," a study of the genetics controversy in the 1970s when some scientists saw potential danger in recombining genes from different species.
Musical credits: Wrote talking blues song about anti-ecological strip mall blight of central Florida (performed only in front of family).

Krimsky's passion began when he was a junior faculty member at Tufts and a company tried to quash a report his students had prepared on the possible pollution of a local water well.

In what other ways, he began to wonder, did companies interfere with or try to direct scientific research?

First, he put together a national database to find out how many academic scientists were closely involved with the emerging biotechnology industry. He found that from 1985 to 1988 more than 800 biomedical and agricultural scientists had served on company advisory boards or had started their own companies. Topping the "Krimsky index" were MIT, Stanford, and Harvard, with 31, 20, and 19 percent of their biomedical faculties with formal business ties.

Next, Krimsky teamed up with a colleague at the University of California, Los Angeles, to find out if corporate involvement was evident in the scientific literature. They looked at one year of articles in the 14 top science and medical journals published by 1,100 Massachusetts researchers. One in every three studies had at least one main author with a financial interest in the outcome of the study — either by acting as a scientific adviser to a related company, holding a patent or pending patent, or being a corporate officer or major stockholder.

In a third investigation, Krimsky and his UCLA colleague found only about 16 percent of the 1,400 most influential journals required authors to disclose financial conflicts. Only 300 out of 60,000 articles published in 1992 listed any potential conflicts of interest, and 66 percent of those journals had no disclosures.

"We were incredulous," Krimsky said. It amounted, he said, to a "don't ask, don't tell" policy among researchers and journal editors.

His work has had ripple effects across the scientific community and in the public perception of research.

"His contribution has been immense," said Drummond Rennie, adjunct professor of medicine at the University of California at San Francisco and an editor of the Journal of the American Medical Association. "He's worked for years on this and built a solid reputation. Instead of gassing off about it, he actually has data. In the end, the only thing that changes things is to keep saying it, publishing it, demonstrating it, lecturing on it, and gradually change people's views."

Many of Krimsky's most steadfast critics are the researchers he's pointing toward. Those critics say a check in the mail does not equate to a skewed result, and that a corporate-research relationship is not always bad.

"Industry needs scientists to create innovation and preserve high standards in technology, and they should be welcomed by the rest of the scientific community as participants in the public domain of science through publications, conferences, and patents," William A. Edelstein, a former researcher at General Electric, wrote in response to a recent magazine piece by Krimsky. "Challenge their work by all means, but please don't dismiss them simply because they work for a company. Unfortunately, too many academics have that prejudice."

Krimsky said he doesn't place all the blame on the scientists — but he's concerned about a university system that is allowing itself to be more and more compromised by corporate interests.

"The deeper issue requires a change in the incentive system," Krimsky said. "One that recasts the moral infrastructure of academic medicine so that journals can have a large reservoir of independent experts who have no financial links to the products and therapies they study."

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MEMORANDUM

TO: Meeting Participants

FROM: Janet Fries
Michael J. Remington

DATE: December 30, 2003

RE: Luncheon Meeting Concerning Legislative Issues of Interest to Universities, Non-Profits and the Pharmaceutical Industry

Public policy and governmental relations representatives of various university, technology transfer and medical research associations and of individual universities as well as representatives of the Pharmaceutical Research and Manufacturers Association (PhRMA) met informally on December 12, 2003 at 11:50 a.m. at the offices of Drinker Biddle & Reath LLP in Washington, D.C. The purpose of the meeting was threefold: (1) for the attendees to become reacquainted since last February's meeting; (2) for the attendees to meet representatives who had not attended previous meetings; and (3) for the attendees to discuss current public policy proposals and legal movements affecting the pharmaceutical industry and the university community both domestically and internationally. In doing so, participants hoped to communicate with each other about the policy goals and prerogatives of their respective organizations. Finally, the participants celebrated the 23rd anniversary of the Bayh-Dole Act. The meeting terminated at 2:05 p.m.

Present at the luncheon meeting were the following:

- Andy Cohn, Director of Public and Governmental Relations, Wisconsin Alumni Research Foundation (WARF)
- Suzanne Day, Director of Federal Relations, Harvard University
- Susan Kling Finston, Associate Vice President, Intellectual Property, Middle East/Africa Affairs and South Asian Affairs, PhRMA
- Janet Fries, Esq., Drinker Biddle & Reath LLP
- Angela Godby, Assistant Vice Chancellor of Federal Relations, The University of Texas System
- Norman Latker, Esq., Browdy & Niemark
- Kamala Y. Lyon, Senior Legislative Analyst, Office of the President, University of California
- Kim Nerres (in place of Diane Auer Jones), Legislative Associate, Princeton University
- Michael J. Remington, Esq., Drinker Biddle & Reath LLP
- Helen Rhee, Senior Director, Federal Affairs, PhRMA
- Jon Soderstrom, Managing Director, Office of Cooperative Research, Yale University (participated by telephone)

DC/394684/3

- Sheldon E. Steinbach, Esq., Vice President and General Counsel, American Council on Education (ACE)
- Marilyn Berry Thompson, Director, Governmental Relations Department, Jorden Burt Boros Chicchetti Berenson & Johnson LLP (representing the University of Virginia).
- John Vaughn, Executive Vice-President, Association of American Universities (AAU)
- Valerie Volpe, Senior Director-Alliance Development, PhRMA
- Sarah Walkling, Associate Director of Federal Relations, Vanderbilt University
- Patricia Harsche Weeks, Vice President, Planning and Business Development, Fox Chase Cancer Center; President, Association of University Technology Managers (AUTM).

OPENING REMARKS

Mike Remington welcomed all participants to Drinker Biddle & Reath. He recognized Sheldon (Shelley) Steinbach and Valerie Volpe as co-chairs of the meeting. Mike noted that Valerie had acted as host for the first meeting; that Shelley had acted as host for the second meeting; and that this was the third meeting.

Shelley Steinbach also welcomed all participants and noted the need for cooperative effort despite the diversity of interests. Sheldon invited each participant to give a brief self-introduction.

[Self-introductions followed].

PRESENTATIONS

Helen Rhee: "Medicare Reform: Hatch-Waxman Act Amendments, Reimportation"

Helen Rhee described the recently-enacted amendments to the Hatch-Waxman Act (the "Act") and explained that companies producing generic products could rely on pharmaceutical companies' data, but could not market a generic product so long as a valid patent exists. One provision of the amended Act is a 30-month stay to innovators. Until patent litigation is finally resolved, there will be only one stay of 30 months, with litigants being grouped. There will not be multiple stays.

In an effort to get products to market faster, generic companies wanted to impose a 45-day window during which innovators would decide whether or not they would defend a patent by filing an infringement suit. Given the 20 year term of patent protection, forcing a decision in such a short period is, in Helen's opinion, an unconstitutional taking. Helen remarked that patent infringement is a "huge deal"; a patent is the reward for all the failed studies. An infringement by a generic can take this reward away.

Generic companies wanted and received declaratory judgments. There has to be a case or controversy before a declaratory judgment can be issued. The Medicare Act provides 180 days

as a generic exclusivity period. Multiple generics can benefit so long as all file suit on the same day.

The goal of the Act is to speed up the litigation process and to encourage generics to bring suit faster. But this provision can backfire to create delay for some generics. The Act also gives authority to the FDA to put products, like topical ointments, on the market quicker.

The law has always provided that any patent holder is eligible for treble damages upon a finding of willful infringement. The generic companies wanted to treat holders of drug patents differently from holders of all other patents, to make them ineligible for treble damages. The generics lost on this proposition. There is no separate treatment for holders of drug patents.

A provision addressing the fear that the brand-name pharmaceutical companies are making deals with generics to keep them off the market was added to the Act. The Act now requires that agreements be recorded with the FTC and the DOJ. So, anti-competitive deals will be avoided.

Helen took the opportunity to discuss other issues of potential interest to the group. Recently, legislation through appropriations has arisen more frequently. Foreign price control (reimportation) is an example. Pilot programs can be dangerous if people get inferior imports. Also, government price-setting is contrary to Bayh-Dole, and may serve as a disincentive especially with rare-disease type drugs. Helen told the group that Senator Hillary Clinton supports the notion that the government knows best; she wants cost effectiveness to be included in labeling. Senator John Edwards has also proposed an amendment, to require drug-to-drug comparison trials, rather than just safety and efficacy, prior to FDA approvals. PhRMA's position is that comparisons are better done by doctors than government. PhRMA asserts that the FDA is not equipped to make economic decisions (or decisions that doctors should make) and that requiring the FDA to make economic decisions would use resources and further slow the approval process.

Andy Cohn asked whether the provisions affecting universities discussed at the last meeting were enacted.

Helen said "no". After an Orange book listing, dual cause of action was inefficient. So, under the Act, a patentee is given 45 days from a generic's notice of application to the bring the 271(e)(1) lawsuit.

Senator Hatch believes there will be pressure to address biologics, but Helen believes that science is not there yet for abbreviated studies involving biologics. Senator Kennedy has voiced concern about human subjects. Helen fears that if a provision such as that proposed by Senator Kennedy was enacted, it would hinder clinical trials. Helen said that there was Republican opposition to this and other proposed restrictions.

Sheldon Steinbach: "The Joint Committee of the Entertainment & Educational Communities:

Lessons for the Technology Transfer Industries"

Shelley expressed the view that it is appropriate to explore together germane issues for higher education and pharmaceutical companies. He noted that a broad range of issues binds us together.

Shelley referred to the Joint Committee of the Higher Education and Entertainment Communities as a successful effort. It is a parallel track in the copyright area. According to Shelley, cooperation between the RIAA, MPAA, ACE and AAU on downloading and file sharing by students makes sense. So does cooperation in the patent area. "This impacts us, too." Otherwise, business connections and opportunities may be obscured by traditional behavior.

Higher education needs to build support and gain political savvy. Shelly noted that higher ed institutions are corporations at the end of the day and suggested that they reach out and cooperate with pharmaceuticals on collateral regulatory matters of mutual concern. He noted that there was nothing binding to meeting. The underlying hope is to find allies and work with them on issues of common concern.

Mike Remington paraphrased from a recent email (from David Korn (AAMC)) about what is the purpose of this group. Mike took the opportunity to explain that it is informal and non-binding. He agreed with Shelley. Mike also posed several questions. He asked the group what direction the meetings should take: Should we do less? Or more? Widen group? Include more invitees? Invite guests speakers? Cross-fertilize ideas? Mike identified the main goal of the meetings as preserving Bayh-Dole. "A blood oath: we will work together to preserve Bayh-Dole and technology transfer."

Andy Cohn observed that PhRMA is an effective partner. A powerful message is sent to policy makers by our alliance. We are more effective together than alone. Consider the ineffectiveness of the university community on the Weldon amendment.

Shelley Steinbach added: "We need a better alert system. What did we lose?"

Andy Cohn added that in the end, we lost on the Weldon amendment because we allowed an amendment with no definition to go into an appropriations bill. Stem cell patents that have already been granted are fine, but we are vulnerable from right-to-life legal attacks on stem cell and genetic areas. That's a big thing to lose.

Mike Remington noted that losing a patent law reform on an appropriations bill is extremely rare.

John Vaughn inquired: "How bad is the Weldon amendment?"

Mike Remington answered that the Conference Report states that past patents are not affected but that leaves the future vulnerable. He also noted that the proponents of the Weldon amendment will attempt to codify it next year.

John Vaughn told the group that he had attended a NIH meeting yesterday with Jon Soderstrom and heard the disturbing remark, "patents kill babies". John said that there is an undercurrent, a feeling that universities are avaricious about patents. John remarked that getting rid of Bayh-Dole would impede progress. "We need it."

Mike Remington predicted that attacks on Bayh-Dole are growing. This is a good time to look forward to 2004. Let's hear a forecast from a PhRMA perspective.

2004 Forecast – PhRMA Perspectives

Susan Finston noted that the head of the USPTO (James Rogan) is stepping down. The threats to Bayh-Dole would be worse if the "wrong" person is made USPTO head when Rogan leaves. The new appointee should not be someone beholden to right-to-life interests. Susan also discussed patent law developments in Europe and in multilateral organizations.

Andy Cohn observed that for stem cells the language in European provisions is better.

John Vaughn noted that the UN is pushing prohibition on therapeutic cloning in international fora.

Susan Finston explained that developing countries have reasons to oppose broad patent protection. The UN Millennium Project is a diatribe against patents and pharmaceutical companies. We are under a continuing threat. We are the gift that keeps on giving. Susan discussed the WTO decision on paragraph 6 of the Doha Declaration in the TRIPS Agreement and public health. The Perez Motta text supposedly clarified new ground on the relationship of the TRIPS Agreement and public health policies. As shown in the article by Paul Van Doren, fertile ground remains for debate on international trade organizations. Paragraph 6 permits exceptions to a rule that doesn't exist. Compulsory licenses for public health purposes should not be permitted.

Susan expressed concerns about Canadian compulsory licensing. She stated that products coming in from Canada are more of a concern than products coming in from India. Susan noted that the US did not join the CDB because we were concerned that disclosure of where material came from would be a barrier to research. An open-source debate is occurring within the WIPO. According the Susan, the US faces three threats: first, attempts to limit patentability (such as disclosure requirements); second, benefit-sharing as a land grab effort; and third, Canadian compulsory licensing.

2004 Forecast – University Perspectives

Mike Remington asked who is looking out for the interests of higher ed? Shelley Steinbach responded: "Good question."

John Vaughn noted that Harold Varmus (former head of the NIH) supported open-source/sharing. Varmus felt that patenting was "too much" of a problem.

Norm Latker stated that the NIH is not supportive of the Bayh-Dole Act. Norm also added that the attacks on Bayh-Dole are nothing new. He remembered that in 1977 there were attacks based on the fear that tech transfer patents would undermine basic rights. Nonetheless, Norm expressed a fear that 2004 would not be a good one for Bayh-Dole.

Patricia Harsche Weeks and Jon Soderstrom: "Technology Transfer: What Should Be Done To Be More Responsive To Policy-Makers?"

Pat Harsche Weeks explained that we face a "schizophrenic" situation between the numbers in the AUTM survey and the public benefit, the latter of which is not just numbers. Pat expressed the view that the technology transfer profession has matured: "We have experienced a significant productivity increase from eleven years ago when AUTM began." Finally, Pat explained that AUTM doesn't take positions when individual members have contradictory positions, such as when faculty may not agree with administration.

Jon Soderstrom said that he thought what is going on in the UN is scary and so is what is going on in Canada. University greed is an issue. Universities have to get their acts together, and not provide ammunition for the attacks.

John Vaughn stated that universities will not be seen as greedy if they plow back profits into research.

Norm Latker noted that we face a serious public relations problem. The Bayh-Dole Act was built on ideals of a free market and patent rights and that the best PR would be to get back to those ideals.

Pat Harsche Weeks passed out copies of a recent Wall Street Journal article that stated that patent holders may be stymieing progress.

John Vaughn noted that charging excessive royalties and patenting things that should not be patented are perceived as problems. Jon Soderstrom added, "and onerous terms in agreements."

Mike Remington suggested that the group work on developing best practices. After all, Bayh-Dole promotes collaboration.

Andy Cohn discussed the CREATE Act. He stated: "We thought we made progress. The AIPLA raised obstacles but then Lilly and AIPLA reached agreement. The agreement, in the opinion of WARF, is workable." Andy also told the group that "co-sponsors in the House of Representatives are needed." He concluded, "enactment of the CREATE Act would be a step

forward; it would remove the sword of Damocles."

Bayh-Dole Act Birthday Cake

Mike Remington presented a birthday cake and set it in front of Norm Latker who he called "the godfather of the Bayh-Dole Act." Mike requested that Norm say a few words.

Norm said that he left government thinking that he had done all that he could and that Bayh-Dole would stand, built on a foundation of logic and a belief in free enterprise and patent rights, but that now he was concerned with the attacks. He said that it is time to return to the foundations on which the Act was built. That approach was successful in beating off the opposition in the past and is likely to succeed again.

Jon Soderstrom noted that right and facts will always win out.

Shelley Steinbach recollected that Norm Latker convinced me thirty years ago that this bill was important for higher education. Recognition to universities for patents was significant. Today, when we consider the basics, we see tremendous societal progress. Twenty-five years ago, government patents were sitting on shelves. Shelley called upon the group to get back to basics. We must fend off attacks which are ever more frequent and more sophisticated.

John Vaughn noted the progress of the last two decades, from twenty (Norm later corrected this number to 75) to over 300 universities with technology transfer offices.

Susan Finston suggested that the community of interests should celebrate the anniversary of Bayh-Dole for two years. That would provide excellent PR.

Jon Soderstrom noted that as a community we have not helped ourselves. We need to train our colleagues. We have to be proactive, and not just reactive. We must make sure people know about the good things we do; that we create businesses, jobs and products. But we have not even convinced our own administrators. We should consider the creation of an educational forum (to teach how to talk to governors and elected officials). We need to teach ourselves how to talk in order to turn it around. We need to make a committed PR effort.

Pat Harshe Weeks stated that Taiwan and Japan have versions of Bayh-Dole. So, it goes around the world. We are in a continuing maturation of the profession.

Jon Soderstrom summed up by stating that we need meetings like this to share thoughts and to be sure that we have a consistent message that does not get misused.

Andy Cohn noted that the Wisconsin program is, in part, a partnership of GE and the university. It is a true collaboration. Royalties flow from GE to the university. We should celebrate success stories like these.

CLOSING REMARKS

Valerie Volpe: "Where Do We Go from Here? Regional Conference, Hill Briefings, Media, Cross-Fertilization"

Valerie Volpe closed the meeting by noting that onerous proposals to amend Medicare had been staved off by collaborative relationships. She pointed out how effective it could be to form alliances and for organizations to say "this will bring harm to us, but it will also cause harm to others you care about." Valerie said it was important to get university representatives on the Hill, to do something concrete regarding abstract concepts and to make people understand the consequences of taking away patent protection. Taking away patents will not bring prices down. Valerie said that PhRMA is ready to support joint activities. She also suggested that the press be invited to universities to be educated about technology transfer and intellectual property.

Valerie remembered that the approach taken by PhRMA with Hatch-Waxman (i.e. denial, and not discussing it) was not a good approach. We must counter the negative information. We must bring the GAO report to life. The AUTM survey must be brought to life. Valerie extended the offer for PhRMA to help universities, and suggested that PhRMA could "match up" with universities on issues.

Pat Harsche Weeks informed the group that AUTM had received a three-year commitment of funding from the Ian Kaufman Society for the purpose of finding an Executive Director (AUTM's first paid position), improving the AUTM survey, developing branding and improving PR, and putting together an executive forum in the fall to direct public policy.

Mike Remington thanked everyone for coming, thanked the co-chairs in particular and expressed the hope that people found the meeting to be valuable and would come to the next meeting.

SUMMARY OF CONSENSUS ITEMS

- Continued cooperation/collaboration between higher education and pharmaceuticals should continue. In particular, the parties should consider joint Hill visits and briefings.
- A committed public relations effort should be developed. Parties should engage in public relations on the Hill and in the press, with a goal of making the abstract become concrete. An educational forum should be considered.
- Success stories about technology transfer should be recognized on a local basis by individual universities.
- Best practices should be considered to avoid mistakes that could harm technology transfer.

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Date: 2/26/04 7:38PM
Subject: AUTM Mtg: Thursday's schedule

According to preliminary counts, this year's annual meeting will have record attendance! Your participation contributes much to the success of this meeting and we greatly appreciate the efforts all of you have made to be in attendance.

Following is a schedule of where you need to be on Thursday, March 4.

Thursday, March 4
7:45 a.m. - Meeting to finalize session (pick-up coffee in Salon E on the way) - Conference Room 8

Noon - Lunch with Birch Bayh and AUTM leaders - Salon E (reserved tables)

1 p.m. - Visit the Networking Fair and Technology Exchange - Salon I

2:45 p.m. - Rehearsal for the plenary session - Salon E

3:30 p.m. - Plenary session begins - Salon E

6:30 p.m. - Welcome Reception - Salon E

And don't forget about the final closing dinner on Saturday night. It promises to be quite a party!

Also, I recommend that you check in at the AUTM registration desk on Wednesday evening between 3 p.m. and 7 p.m. By picking up your badge on Wednesday afternoon, you will avoid long lines at the registration desk on Thursday morning.

Please let me know if you have any questions. I look forward to seeing all of you in San Antonio!

Regards,
Denise Y. Baran
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1. The water-proof towel
2. Glow in the dark sunglasses
3. Solar powered flashlights
4. Submarine screen doors
5. A book on how to read
6. Inflatable dart boards
7. A dictionary index
8. Mechanical Pencil sharpeners
9. Powdered water
10. Pedal-powered wheel chairs
11. Waterproof tea bags
12. Watermelon seed sorter
13. Zero proof alcohol
14. Reuseable ice cubes
15. See-through toilet tissue
16. Skinless bananas
17. Do-it-yourself road map
18. Turnip ice cream
19. Toe implants
20. An all white flag
21. Rolls Royce pickup truck
22. Helicopter Ejector Seat

In the 1980's, French women Dominique Peignoux, Yvette Guys and Francoise Dekan marketed a musical napkin that was placed inside a baby's diaper and played "When the Saints Go Marching In" as soon as it became wet.

William A. Calderwood of Peoria, Arizona patented helium filled furniture that would float to the ceiling when not in use to allow extra floor space and be pulled back down by a rope as needed.

It was in 1966 that America's Thomas J. Bayard invented a vibrating toilet seat, acting on the belief that physical stimulation of the buttocks is effective in relieving constipation.

James Moreau developed a brassiere in 1988 which surrounds the breasts with water, so that a buoyant force provides improved and independent support for each breast. A transparent version is suggested for those who wish to make a fashion statement.

In 1984, Inventor Timothy Zell developed a method of growing unicorns that are of higher intelligence and physical attributes, They are also said to be useful as a guard animal. What you may not want to know is the method involves surgical alteration of a one-week old goat, so that its two horn buds will grow together.

http://www.ozjokes.com/jokes/jokes.aspx?jokeid=1276

"Commanded on solicited the resources necessary"
S.B. Morse, Edison, Bell, ~~[illegible]~~
mechanical + electrical Arts
Ehrlich - life sciences.

Cottrell — recognized that an increasing number of scientists [illegible] were not in position to command on solicit application. Created Research Corp. to ~~assist them~~ and recognized that their main ~~assist to~~ attraction obtaining resources to obtain such resources were the ownership rights provided to inventors under the Constitution.

WAPF — (930's) - No [illegible] to assist [illegible].
Fleming — Gov't involvement — Atomic energy! — brought application
Vannevar Bush
Flood of research foods after WWII.

Attorney General
Shannon - Endicott note
failure of policy
Policy embed in bureaucracy
willing to publicly embarrass
investigations that challenged it.
Cade - G.A.O. instigated + assisted by those who

required
ID of Tech
management
sharing Royalties
w/ inventor.

institution patent agreement
— spreading to other agencies
by ~~admin~~ administrative req.
Nelson hearings
Attempts to legislate uniformity
Califano edict
Flash point
legislate institutional
patent agreements

NEXT

SUPA Meeting
February 6, 1984
Washington, D.C.

RESEARCH AGREEMENTS AND THE LONG TERM

by Edward L. MacCordy
Washington University

Collaborating with industry on research programs they sponsor in the university has proved to be an interesting and productive experience for us at Washington University, and we believe for the companies involved. On the whole these research arrangements have involved us in a variety of situations different from our long and continuing experience with government research sponsors. We enjoy the close, cooperative working relationship which has developed with company management, their scientists and even their attorneys. There have been problems but working them out has proved the original intent of both parties, that these be truly collaborative programs. And let's not forget, this is a relatively new experience, one from which we are continuing to learn.

For example, we have two major hybridoma contracts which will expire this year. They have provided us with about $5½ million in research support for three years. The research has been very successful, producing more output than the company labs, production facilities and marketing systems could absorb. Compounding the situation, the product objectives of the companies have changed. Continuation of this line of research into the future is no longer compatible with corporate development plans. So, we have been exploring the alternatives of continuing the program under sponsorship of one or more new companies, or possibly instigating a research and development limited partnership which would provide $12-$15 million in contract support for a five year period.

In another case, our $25 million, five year biomedical research program with Monsanto, the venture has been pleasingly productive as indicated by a constantly increasing presence in our laboratories of their patent attorneys. The other day I was told they anticipate a need for 2½ patent attorneys full time to deal with the research output.

These industrial research contracts essentially represent the integration into a single cooperative venture of activities which previously were separate and independent. These agreements provide (1) support for a broad area of scientific research, (2) a faculty proposal system, (3) a collaborative peer review project selection process, (4) a company monitoring system for early detection and disclosure of inventions (both patentable and not), (5) a process for the immediate filing of patent applications by company attorneys in the university's name, (6) cooperative efforts between our scientists and theirs to transfer the technology to their labs for scale up and commercialization, and (7) an established framework, including basic terms, for licensing any new technology to the company. It's a comprehensive, efficient and productive arrangement for technology creation and transfer which is especially cost effective for the university. But, this approach to technology transfer is not necessarily adaptable to all areas of science and technology nor to all companies, even major ones.

So, today, I would like to deal with industrial sponsorship of university research in the context of a set of technology transfer methods, as only one of the productive methods available in conducting that total transfer process. The agenda of this meeting treats some other elements of a comprehensive technology transfer program. All are useful in the right circumstances, and there are always new concepts on the horizon which will find their proper place in time.

To understand and appreciate where universities are today and especially where they are heading in their technology transfer activities, it is helpful to understand the history of developments in this area.

The early days must have involved a very few mavericks dedicated to bringing research results out of the university lab for public benefit; men who realized that publication in scientific journals, though very desirable for other reasons, none the less represented an ineffective transfer method devoid of incentive for anyone but the university scientist.

In 1912 Professor Cottrell used his patents on the electrostatic precipitator to establish Research Corporation which continues to provide patent management service to educational institutions to this day. I believe one of my neighbors, St. Louis University, used Research Corp. many years ago to obtain and manage a vitamin patent which thereafter provided support to the university's department of Biochemistry for years. Like all of us though, Research Corp. had bad days as well as good in this game of technology roulette. At one time it had assigned to it by MIT the Forester invention on the magnetic core used in computer memory devices. Apparently in the 1950's not desiring to do battle in court with IBM, the invention was reassigned to MIT which went on to settle the case and earn millions on one of the biggest financial winners in university history.

Of course much earlier, in 1925, the unique and famous WARF, the Wisconsin Alumni Research Foundation, was founded with assets of $900 and Professor Steenbock's vitamin D invention. WARF has been fantastically successful with at least two big winners, Vitamin D and Warfrin, and has paid over 100 million dollars to the University of Wisconsin since its founding, an exceptional feat. However, it should be realized that the WARF success story is not one of patent management alone. In those early days the director was not so foolish as to dissipate his major royalty income by investing it

solely in the university's research. No, he played the stock market and built up a critical mass of investments for WARF endowment. To this day WARF possesses a major endowment and is an active venture capital investor in local companies. Although royalty income produces a million dollars or so a year for the university, investment income trebles or quadruples that amount.

There is only one WARF and it has courageously done what few of us, except MIT and in the near future maybe Stanford, would entertain doing, becoming involved in major litigation. Currently it is a co-defendant in an $82 million product liability suit and going back to 1944 it was involved in infringement and invalidation litigation over the vitamin D patent. As an interesting sidelight concerning the practice of field-of-use licensing, since WARF was in the great dairy state of Wisconsin, oleo-margarine manufacturers were denied licenses to this patent. So much for mixing politics and patents.

This brings me to the mid 1960's, to what might be termed the start of the 15 years struggle for ownership by universities of patents derived from government sponsored research. A famous GAO study of that era concerning the use of results from research in medicinal chemistry, reported that industry would no longer cooperate in commercializing new drugs from HEW research and interest by university's scientists in developing new drugs was decreasing. At that time HEW was very resistant to patenting and exclusive licensing of inventions. Instead, the Department preferred to dedicate inventions to the public through the publication process thereby making them freely available to all. In taking this position HEW relied on a 1924 opinion of the Attorney General that agencies could not grant exclusive licenses under government owned patents without specific statutory authority. This question was to reappear in litigation in the mid 70's.

This GAO study resulted in a new and enlightened era at HEW focused on the extensive use of a liberal Institution Patent Agreement, the famous IPA's which technically still exist. Norm Latker, then Patent Counsel for HEW, administered the IPA program in such a manner as to develop a nation-wide interest by universities in patent management. Through his efforts a productive relationship between universities and HEW was developed based on mutual respect and cooperation. In not too many years Norm's extraordinary dedication would come very close to costing him the loss of a lifelong career of outstanding government service.

By the early 70's the number of experienced university patent administrators was still small but there was a sizeable group of us eager to learn and to seek massive riches through licensing for our institutions in the grand style of WARF and MIT. These administrators started getting together in Chicago at the University/Industry forums put on by Dvorkovitz and Associates. At these forums they could present their patent portfolios, if any, to licensing representatives from industry and had an opportunity to learn how companies handled the licensing of new technology. Above all else they made valuable personal contacts in industry whom they could call on for assistance in the future.

Organized and effective communication among university patent administrators, of which this meeting is a continuing part, commenced on October 15-16, 1974 at a special gathering on Technology Transfer organized by Allan Moore at Case Western Reserve University. About 100 university administrators attended along with representatives from government and interested patent management firms including Research Corp, Dvorkovitz, Battelle Development Corp., and Arthur D. Little. Discussions started at that meeting continue to this day on such fundamentals as institutional patent policy, organization of the patent administration function, evaluating disclosures, filing patent

applications, and how to market inventions and draft license agreements. It is notable that Howard Bremer's caution to the attendees, that on average only one out of five hundred disclosures would ultimately produce income, did little to discourage us. Apparently the odds have improved with time. Another momentous event occurred at this meeting. Quietly and without announcement, a few of the attendees met in a back room and founded this SUPA organization.

About this time several major events occurred which would severely impact university technology transfer. Almost unnoticed until years later, at least in the technology transfer field, was the development in 1975 of hybridoma technology by Kohler and Milstein in England. The biotechnology revolution was well under way. For better or worse these English scientists were not as fortunate as Professors Boyer and Cohen. They did not have a Niels Reimers rushing to the British Patent Office to establish their ownership of this new revolutionary technology, not even in their home country.

The year before in 1974, three court cases of overwhelming importance attracted the attention of every university patent administrator. These were the two Public Citizen cases involving the General Services Administration and the case of Washington Research Project vs. HEW Secretary Weinberger. The plaintiffs in all three cases were Mr. Nader's consumer advocate organizations. The first two cases essentially claimed that exclusive licensing by a government agency of a government owned patent was illegal because it involved the disposal of government property without statutory authority. The court ruled in favor of the plaintiffs which could have resulted in the termination of all Institutional Patent Agreements with universities and the voiding of all licenses of inventions derived from government sponsored research. Fortunately the ruling was overturned on appeal but only on a technicality. The Nader forces could have refiled the case and probably would have won. The

The need for Patent legislation was becoming urgent.

The Washington Research Project case involved the issue of whether university research proposals could be withheld from release under the Freedom of Information Act using the "trade secret" exemption, i.e., the 4th exemption. Of course one risk was that if research designs contained in proposals were instantly releasable to the public on request, this might well constitute publication under patent law. The court ruled that research designs submitted in grant applications were not exempt from disclosure since, in the words of the court, "it defies common sense to pretend that university scientists are engaged in trade and commerce." A footnote in the decision saved the day by stating that the possibility of commercial activity was not absolutely precluded simply because no evidence of it had been presented by the Government in Court. Thus was laid the somewhat shaky basis for administrative case by case determination concerning public release that is still in use.

In a brief description I cannot do justice to the struggle for statutory authority which took place over the next few years and which finally resulted in the passage of PL 96-517, the University and Small Business Patent Act. Norm Latker, Howard Bremer, Niels Reimers, Roger Ditzel, Art Smith and many others fought a multi year uphill battle against some of the strongest forces in this town, including powerful Senators and Congressmen, Ralph Nader, Admiral Rickover, and the leading patent counsels of various Government agencies. Victory finally came with the passage of PL96-517 in 1981 and was quickly followed by a final skirmish with patent attorneys from several mission agencies still determined to salvage what power they could during the drafting of implementing regulations, now OMB Circular A-124.

A fresh, invigorating era was dawning for university technology transfer. Everything seemed to be falling into place just at the right time. The Carter Administration's Domestic Policy Review had focused the nation's

attention on lagging innovation and productivity, and had identified what was termed a "gap" in research relations between the country's universities and industry. PL 96-517 blessed exclusive licensing by universities thereby removing industry's long held concern over possible loss of exclusive rights from research they might sponsor in universities. No longer need they fear contamination of their invention rights by closely related government sponsored research, a fact that made universities a much more attractive research resource.

The climate was further enhanced by changes in the tax law designed to encourage industry to undertake more research. Special R&D tax benefits were offered for industrial investment in university research. But beyond that the tax code now encouraged the formation of research and development limited partnerships, a means to stimulate a greater national investment in R&D beyond that being made by government and industry.

Finally, the biotechnology revolution was ushered in by the new technologies of hybridomas and genetic engineering. The 1980 Chakabarty decision by the Supreme Court cleared the way for patenting of the new life forms which would be produced from these revolutionary technologies. Universities would be essential players in the high stakes biotechnology game since their biological scientists were now a scarce, valuable and essential resource. The same phenomena had occurred briefly and on a smaller scale a few years earlier when computer and X-ray technologies were merged to produce the computerized tomographic scanner and computer scientists at several universities found themselves highly valued by X-ray companies. But the biotechnology revolution would bring both opportunities and challenges of a type and scale never before faced by universities.

Niels Reimers would extend his role as a leading innovator in patent management by filing and prosecuting the basic and somewhat controversial Boyer-Cohen patent applications, technology which would quickly earn a couple

of million dollars in licensing fees for Stanford and Cal. Whether he has a tiger by the tail is yet to be seen but most certainly this will be a benchmark example for university patent administrators.

Steve Atkinson would suffer through Harvard's proposal to join with their Professor Patashne and others in the creation of another Genentech ending up two years later with an offer instead to 200 companies to license the Patashne patents, resulting in a somewhat disappointing response from industry.

Agrigenetics would raise $55 million under an RDLP and pose new and different licensing issues for a dozen or so universities who were the recipients of the RDLP's research contracts.

Multi-million dollar research contracts which had appeared earlier between Exxon and MIT, and Monsanto and Harvard would suddenly pop up at Massachusetts General Hospital, Washington University, Rockefeller University University and elsewhere, inviting Congressional and press skepticism about the University's ability to avoid corruption except under government sponsorship.

And all the time with little fanfare the universities continued development of programs to license the technology derived from research sponsored by government and other non-commercial organizations.

It is appropriate now to reflect on what universities should be accomplishing and how this can best be done. Ten years ago at the Case Western Reserve meeting Howard Bremer observed that our purpose was not necessarily to make money for the university but to transfer technology for public benefit. In a 1980 article Niels Reimers reported that with few exceptions a University Licensing Office is economically viable only if one or more "big hit" inventions come along. It should be obvious by now that both patent and research administrators should employ the most cost effective transfer arrangements. Further, they should be concerned with more than just obtaining and licensing patentable inventions for the purpose of enriching their institutions.

Our university laboratories are staffed by over 50,000 innovative, doctorial level scientists and engineers engaged in creative research and development in every field of technology, not just biotechnology. Patent and copyright licensing is of limited effectiveness by itself as a technology transfer method, as is publication in professional journals. Research collaborations with industry add another dimension to technology transfer of significant value in certain situations.

But the opportunities which lie ahead may enhance university technology transfer beyond what we presently can imagine. In the future RDLP's may be used extensively by universities to finance research alliances with the small, capital-poor, but extremely energetic and innovative high tech companies in many fields. Multi-million dollar RDLP's and venture capital pools are being proposed (one talks of a $1 billion dollar fund) to finance appropriate research at a consortium of universities with the intent of transferring patented and unpatented intellectual property to start up companies created, staffed and financed by the general partner or venture capitalist. Could this help us to retain our faculty members if we would take and share equity positions in lieu of royalties? Will such high tech ventures put greater emphasis on the commercial potential of new technology and less on its patent potential.

I am confident that more new ideas will appear soon. Such opportunities are not for the timid or the unimaginative, and take note that they will be accompanied by constant pressure to integrate university research and intellectual property administration, one way or another.

Idle dreaming? Ten years ago at the Case Western Reserve meeting much of what you are discussing in the SUPA program here, today and tomorrow, as well as what is actually happening now in university technology transfer, would have been dismissed as impractical or objectionable, or both.