ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS

NEWSLETTER

September 1996

Comments on NIH's New Biological Materials Policy

by Joyce Brinton, Harvard University

If your institution receives research funding from the National Institutes of Health (NIH) and you have not already done so, you should take careful note of the new "NIH Procedures for Handling Non-Election of Title to Unpatented Biological Materials" which appeared in the NIH Guide on May 17, 1996. These Procedures set out what recipients of NIH grants need to do regarding reporting those "Subject Inventions" which are biological materials and on which they do not plan to file patent applications, but do plan to license commercially. A copy of the Procedures is an insert to this issue of the Newsletter.

Since the Procedures were published, AUTM and COGR have been working with NIH to clarify what NIH's expectations are and what Technology Transfer Offices would need to do in order to meet those expectations. The result of our efforts is reflected in the questions and answers included in the article below by Sue Ohata of the NIH Extracurricular Invention Reporting Office. The most important point to note is that if biological materials are created as part of an NIH funded project and they meet the criteria of a "Subject Invention," the grantee institution (you) need to report them to NIH. If you do not plan to file patent applications, but do wish to license the materials commercially, NIH is willing to waive its right to take title provided you follow the May 17th Procedures. In general, these Procedures are consistent with what we, as academic licensing offices, should be doing anyway, but now our offices should make special efforts to ensure that we understand our obligations and carry them out.

Please read the May 17th Procedures and Sue Ohata's article with care and do your best comply with these requirements. As issues or problems arise, please let NIH (Sue Ohata at 301-402-0850) and AUTM (Joyce Brinton at 617-495-3067) know so that further clarification can be provided or changes made if appropriate.

NIH's New Biological Materials Policy

by Susan Ohata, National Institutes of Health

On May 17, 1996, the National Institutes of Health published the "NIH Procedures for Handling Non-Election of Title to Unpatented Biological Materials" in the NIH Guide. A full text of this new policy can be found on the EDISON Home Page (the URL is http://era.info.nih.gov/Edison/). This notice sets forth the NIH policy for allowing contractors and grantees to license biological materials on which the contractor elects not to file a patent application and which are submitted to the NIH for review and possible election of government title under the Bayh-Dole Act. The policy sets forth conditions on which the government will not assert its rights to title to the subject invention.

Members of AUTM, the Council on Governmental Relations, and the NIH worked together to develop the following Q & A to clarify the policy and ensure that universities and other NIH awardees will be able to fully comply with the procedures and NIH expectations.

1) Which biological materials are subject to these procedures?

Only biological materials that meet the definition of "Subject Inventions" included in the regulations implementing the Bayh-Dole Act need to be reported. That definition is as follows: "any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.) ... conceived or first actually reduced to practice in the performance of work under any contract, grant or cooperative agreement [with NIH]."

It is expected that grantee institutions will follow the same decision-making processes for determining whether a disclosure of a biological material qualifies as a "subject invention" as they follow for disclosure of other types of inventions or discoveries. In other words, if the institution determines that the biological material would not

normally not be reported to NIH as a "subject invention," it would not be covered by these Procedures. In such cases institutions should document these decisions in their files.

2) What does NIH mean by the requirement to "address continuing availability of the material to the nonprofit research community" when granting an exclusive license for internal use by a for-profit entity?

Perhaps the simplest way to meet NIH's expectations regarding "continuing availability" is to reserve the right, as part of the exclusive license agreement, for the licensor (the grantee institution) to make the materials available for non-commercial research purposes to nonprofit organizations. Of course, the licensor/grantee institution would need to arrange with the originating laboratory to provide the materials to appropriate researchers at nonprofit organizations so long as supplies of the material are available or can be reasonably produced. Consistent with the Public Health Service policy relating to the distribution of unique research resources, these materials should be provided either without cost or at cost. Clearly this obligation cannot extend forever, but should continue for a reasonable period while the materials are useful to the research of other scholars.

If the grantee institution expects to have difficulty with the preservation of a supply of the material, it might require the licensee to provide a sample of the material to the licensor institution in the event the institution's supply is depleted and cannot be easily replicated. In that way the grantee institution could continue to provide the material to researchers at nonprofit organizations. Another alternative would be to require the licensee to provide the materials to a reasonable number of appropriate researchers at nonprofit organizations, perhaps under material transfer agreements between the licensee and the recipient organization.

3) When does an exclusive license need to "provide for conversion to nonexclusive status or termination of the licensee's rights upon failure to comply with the terms addressing continuing availability"?

If the licensor (grantee institution) has retained the right to make the materials available to other nonprofit organizations, such a provision is generally unnecessary. However, if the only source for the materials is via the license (i.e., if the licensee is responsible for providing the materials to other researchers), then such a clause is required.

4) What is meant by the requirement to provide for "independent maintenance of the material"?

NIH is concerned that if the sole source of the materials is an exclusive licensee and that licensee fails to meet its obligations as to availability, then the materials may become totally unavailable to the research community. Thus, the grantee institution should make efforts to obtain the commitment of the originating laboratory to maintain the materials for a reasonable period. Clearly such a commitment cannot be unlimited since that laboratory might close or the supply of material could be accidentally destroyed or could be depleted and recreating the material (due to cost or manpower constraints) may not be feasible. Depositing the material at a national repository would also meet the requirement. However, it is recognized that there is a cost involved and that an exclusive licensee would undoubtedly require that the licensor insure that access to samples from the repository be limited to researchers at nonprofit institutions conducting noncommercial research.

5) Will the government pay the costs of supplying material to government researchers? What happens if there are no further supplies?

If there are costs involved in preparing the materials and/or in shipping and handling, the university and NIH need to reach an agreement regarding these costs. NIH expects that grantee institutions and the originating laboratories will make reasonable and good faith efforts to supply requested materials to government researchers. Nonetheless, NIH recognizes that occasionally supplies may cease to be available.

6) What happens if NIH utilizes its right "to distribute the material" because of the failure of the grantee institution to fulfill these procedures?

Since NIH's concern is that the materials are available to the nonprofit research community, it would restrict its distribution to that community. An easy way to ensure that NIH retains this right, would be for the university to include in its license agreement a provision that the license is subject to these NIH procedures.

7) Does the grantee institution still need to sign an agreement with NIH for each unpatented biological material it reports to NIH?

Grantee organizations are no longer required to sign a terms and conditions agreement for each patentable biological material they wish to license commercially, but not patent. For those reporting electronically, NIH only requires that you report your decision in EDISON under "Institution Invention Status" within "New Inventions" in the main menu. Others who are reporting with paper should submit a letter informing NIH of the decision to license commercially, but not patent. A confirmatory license to the government must be sent to NIH whether you are reporting by paper or electronically.

1997 Annual Meeting: Broadening Horizons

by Chris McKinney, University of Florida

It's never too early to mark your calendar for the 1997 AUTM Annual Meeting to be held at the Fairmont Hotel in San Francisco, CA, February 19-23, 1997. With a theme of "Broadening Horizons," this meeting will reflect the state of the art in university technology transfer and take advantage of the meeting location. Sally Hines and I along with an enthusiastic program committee have been putting together a collection of meetings, workshops, and related activities which should be both professionally helpful and personally enjoyable. With San Francisco as a venue, we are sure those attending will have an excellent time!

The meeting has a new format this year, beginning on Wednesday with a welcoming reception and ending on Saturday with a delightful dinner. This schedule will allow additional opportunities for networking and visiting scenic locations in the beautiful Bay area and will permit Saturday overnight stays for the most economical flights.

The program opens Wednesday night (February 19) with a welcoming reception which will set the tone for the meeting. The educational tracks will be held on Thursday morning and will feature sessions on intellectual property and commercialization, using the Internet, and copyright, software, and multimedia. The opening general session will take place on Thursday afternoon, with an opening reception scheduled for Thursday evening. The general session will feature a prominent and dynamic speaker with close ties to the region. Mary Watanabe has done a fine job in seeking a terrific speaker who will elaborate on the meeting's theme and place it in context.

Workshop sessions will kick off Friday morning and be followed in the afternoon by special interest group (SIG) sessions. Barry Rosenberg and his workshop committee have done an excellent job of creating a program with more than three dozen sessions. Representative titles include Invention Triage, Alternatives to the Billable Hour, Professional Development within the University Environment, Intellectual Property- A World Perspective, and New Horizons in Multi-Party Research Collaboration. The SIG sessions, coordinated by John Snyder, will serve as a more informal route for the spirited interplay of ideas on a wide variety of topics. The evening will be free- a great opportunity to see San Francisco by night.

Saturday morning will round out the workshop sessions, with a transition to the plenary sessions in the afternoon. Ray Wheatley is working on the plenary sessions with the intent of bringing an industrial biotechnology focus as well as a thrust toward the future of technology transfer. The gala dinner will be on Saturday evening in the Grand Ballroom of the Fairmont with the ever-exciting AUTM Band for entertainment, a memorable event to be sure!

I want to thank everyone who is contributing so effectively to making the 1997 meeting outstanding in so many ways. I would like to offer a special note of thanks to the following for their tremendous service:

Program Co-Chair: Sally Hines
Workshop Chair: Barry Rosenberg
Keynote Speaker Chair: Mary Watanabe
Plenary Chair: Ray Wheatley
Educational Chair: Lou Berneman
SIG Chair: John Snyder
Vendor Chair: Penny Dalziel
Activity (Golf) Chair: Jon Sandelin

What would a meeting in San Francisco be without a city tour? Well, don't bother asking because a wonderful half-day tour will be one activity available during the meeting. As for organized sports, Jon Sandelin has arranged for a golf event that will be one you won't want to miss. See you in San Francisco in '97!

Advanced Education in Technology Transfer

by Lorrie Anthony, Syracuse University

So, you're in the technology transfer field and you're thinking you would like to pursue a graduate program of study to strengthen your background. The first thing you do is check out the AUTM web page for a listing of graduate programs. As you review the curricula of the schools, one thing that is quickly evident is that while all of the programs are interdisciplinary, the majority are joint management and engineering programs while two others are law programs collaborating with the management school.

The reason for the emphasis on management is that high tech firms are looking for managers who can identify, assess, manage, and help bring innovative technologies into the marketplace. Individuals with a strong technological background who understand the role of technology in sustaining the firm's competitive edge have skills that companies need. Most graduate programs in technology management are designed to meet these needs. They are MBA or Masters of Science programs whose course work typically includes accounting, finance, design and manufacturing, marketing, and organizational

behavior.

There are approximately 15-20 institutions that offer masters programs in the management of technology, including Georgia Institute of Technology, Massachusetts Institute of Technology, National Technological University, and the University of Texas at San Antonio. Several institutions offer executive masters degree programs which incorporate much of the same material as mentioned above but are specifically designed for working executives and managers. These institutions include the University of Maryland and the University of Texas at Austin.

Technology transfer professionals in academic institutions, however, require a different set of tools. In addition to a basic understanding of marketing and finance, these professionals require a solid background in intellectual property law covering patents, copyrights and trademarks; contracting and licensing, as well as negotiation skills.

While there does not appear to be any institution that directly meets all of the needs of the academic professional, the two programs with a legal focus come close. The Master's of Intellectual Property at the Franklin Pierce Law Center and the Law, Technology and Management at Syracuse University are interdisciplinary programs offering course work in intellectual property and contracting law and business management. The Syracuse program has its law students incorporate courses covering accounting, financial negotiations, and tax issues into their curriculum.

For those who cannot afford to take off work for one to three years to complete a degree program, there are several institutions that offer short programs that provide skills and training. The US Office of Personnel Management periodically offers seminars on technology transfer issues for federal employees while the University of Baltimore offers a series of courses for graduate students designed to provide hands-on experience of moving technology from the idea stage to the marketplace. Franklin Pierce Law Center has a six-month Diploma program centered on the legal issues of technology transfer.

Unlike ten years ago, there are now a reasonable number of graduate programs directed to developing the technology transfer professional, particularly those who are looking to work in the corporate arena. There will probably be more programs developed as the value of the technology transfer professional is recognized. At this point, however, for the academic technology transfer professional, the best comprehensive training ground remains the AUTM seminars and workshops.

Regional Roundup

Central Region- Connie M. Armentrout, University of Missouri System

Over 200 members of AUTM and the Licensing Executives Society gathered in Chicago from July 21st through the 23rd to participate in the 1996 Central Region Summer Meeting. The sessions were outstanding and the meeting rooms full despite the pull of the sights and sounds of Chicago. My thanks to all those folks who participated on the Planning Committee or that volunteered to help during the course of the meeting.

Following the wrap-up of the 1996 meeting, the Planning and Site Committees for the 1997 meeting to be held in Ann Arbor, Michigan got right to work. Rajni Aneja will be Program Chair for 1997. Please send along any workshop ideas that you might have to her as the group will be meeting in mid-November to draw up an outline of the program for the Ann Arbor meeting. My thanks to Anne DiSante and Mike Kope for all their hard work in getting the site arrangements pulled together. The meeting will be held in the downtown area of Ann Arbor so that the participants will be within walking distance of most of the many sights and activities that Ann Arbor has to offer.

The time has come for the AUTM Board to review the concept of having Regional meetings in the summer (versus an Annual Summer Meeting that would be similar to the Annual Winter Meeting). I would appreciate receiving your written comments on the pros and cons of continuing the Regional Meeting format. I will provide any comments I receive to the AUTM Board at the October 26th Board Meeting.

Again, thanks to all those who participated in the 1996 Chicago Central Region Summer Meeting! Each of you helped make the meeting a success. On behalf of the 1997 Planning and Site Committees, we look forward to receiving your suggestions for the 1997 Meeting!

Western Region- Sandra Shotwell, Oregon Health Sciences University

Interesting and informative talks, an interactive audience, topics of interest- they added up to a very successful summer meeting in Boulder in July. What I have always loved about regional meetings has been the opportunity to get a small group together to exchange ideas, stimulated by the speakers who have arranged their thoughts in advance. The participants valued the meeting enough this year to support doing one in Seattle next summer, even though the annual meeting will be in our region

(San Francisco, February 19-23, 1997). Catherine Hennings will be the program chair and is searching for a location selected by survey of the Boulder participants- "out-of-the-way and near the water." Many thanks to this year's program chair, Michael Gabridge, and the folks who helped plan and carry out this year's meeting. Come join us to help plan or even just attend next summer's meeting - I think you will find it well worth your time.

Canada- Natalie Dakers, University of British Columbia

The recent Canadian/Eastern Regional Meeting held in Halifax, Nova Scotia in June was an informative and enjoyable event. Halifax provided a charming location and those who attended were able to experience some of the culture and hospitality common to the Maritimes. The Program Committee did an excellent job in making sure the meeting addressed relevant issues in technology transfer in both Canada and the US. Colleagues from both countries learned of their neighbor's approach to common challenges and left with new ideas to apply in their work.

The timing of the June meeting coincided with a meeting of the Medical Research Council's (MRC) Executive Committee also being held in Halifax. I was invited to make a presentation on behalf of AUTM Canada at the MRC meeting. I enlisted the support of Teri Willey, AUTM President and James Murray, Chair of the International Committee, to join me in making the presentation. We gave the group an overview of AUTM, discussed some of AUTM Canada's priorities for the coming year and suggested areas of mutual interest between ourselves and the MRC. The MRC was very interested in what AUTM was doing, and it was evident from our discussions that there were various areas where the two groups could work together to achieve mutual goals. The partnership between the MRC and the Canadian Medical Discovery Fund (CMDF) is one obvious area of mutual interest. It may be possible for the two organizations, in cooperation with technology transfer offices, to work together on developing an education program for faculty about the opportunities created by this partnership.

One topic of conversation in Halifax was the diversity of patent policies among Canadian universities. Over the next several months, with your help, I will be gathering information from each Canadian university on intellectual property and patent policies and compiling a comparative summary. It is my plan to have such a summary posted on the AUTM web site so that it can be used as a resource for members and other interested parties. If your Canadian institution has a patent or intellectual property policy, please send me a copy, at my office at UBC. I would also welcome any suggestions or information that any of you may contribute to this project. I would be especially interested in learning of any previous efforts to compile a similar summary.

I hope you have enjoyed a pleasant summer. Please feel free to contact me at any time with any questions. I look forward to seeing you at either the Advanced Topics meeting in Phoenix in December or the Annual Meeting in San Francisco in February. Or better yet, both!

Eastern Region- Mark Crowell, North Carolina State University

The the theme of the Canada/Eastern Region Meeting in Halifax, NS, was "Business Strategies for a Changing Economy," and the program included an impressive and timely array of speakers and topics which were of great interest to attendees from both regions. The program committee is also to be congratulated for incorporating several novel presentation styles into the meeting, including a series of small group "State of Technology Transfer Focus Sessions," with the results of each focus session being summarized and reported back to the all attendees in a plenary session. Registrants for the meeting seemed clearly to enjoy the meeting location and special events as much as the meeting itself. The weather, sounds, sights, and friendliness of Halifax made it a terrific site for the summer meeting. Special thanks and recognition go to the program committee consisting of members of both regions, and especially to the co-chairs, Jeanie McGuire of the Enterprise Development Corporation, and Terry Donaghue of Mount Sinai Hospital in Toronto.

I am pleased to confirm that the 1997 AUTM Eastern Region Meeting will be held in Portland, Maine, the very popular site of the 1995 Eastern Region Meeting. The dates for the meeting will be June 29 through July 2, 1997. Patricia Harsche of the Fox Chase Cancer Center has agreed to chair the program committee for the 1997 regional meeting. Enterprising AUTM members in the Eastern region will, I'm sure, be quick to recognize that the meeting is scheduled to end on Wednesday, July 2, and that by tacking on one day of vacation, it will be possible to enjoy a long Fourth of July holiday weekend in Maine.

As I mentioned in the March Newsletter, I am firmly committed to facilitating the involvement of Eastern Region members in AUTM activities- especially among members who previously have not been particularly active. I want to again urge you to contact me (mark_crowell@ncsu.edu) if you are interested in becoming involved. Finally, I am pleased to report that the Eastern Region continues to add new members to AUTM at an incredible pace. Since February of 1996, 55 of 117 new AUTM members are from the Eastern Region.

A Prior Art Speed Trap on the Information Superhighway

by Phillip B.C. Jones, Foley & Lardner

The popularity of the Internet has encouraged the rapid growth of a new storehouse of knowledge that a recent court case stated "is effectively part of the public domain, impossible to retrieve" (Religious Technology Center v. Lerma, 1995). This development poses a challenge to those concerned about patent rights, since, as part of the public domain, Internet-accessible information is considered prior art, a key standard for a determination of patentability.

There are two aspects of Internet electronic publication that a technology manager should consider when evaluating its effect on the patentability of an invention. First, it is possible that the inventor distributed information that may only be found via Internet and in no other form. For example, information posted to news groups may be located only by searching an Internet archive and a few peer-reviewed electronic journals are published that lack corresponding paper counterparts. Hence, it is important to verify with an inventor all communication about an invention that may be considered available to the public.

The second point to bear in mind is that scientific information can be distributed more rapidly via Internet electronic publication. As an illustration, many on-line versions of traditional paper publications post material on Internet before mailing the paper counterpart to subscribers. A recent look at such on-line journals and a survey of their editors revealed the following examples:

- Protein Science places the table of contents and abstracts for each issue on Internet about four weeks before publication of the paper copy;
- Development posts abstracts for each issue about six weeks before the publication date of the paper journal; and
- Blood Cells, Molecules & Diseases places the full text of articles on Internet about seven days after receipt of a manuscript by the editorial office, or about nine weeks before the mailing of the paper copy of the journal.

Consequently, an on-line journal can accelerate the effective publication date of disclosure that is also published in a paper journal. In fact, even on-line journals, such as Genes & Development and Biochemical Journal, that post abstracts or full text on the mailing date affect the actual publication date of the material. This is so because, under U.S. patent law, a paper journal is effective as prior art on the date that it reaches the addressee, not on the date of mailing.

It is important, therefore, for a technology manager to be aware of Internet distribution policies of specific journals when he or she is discussing potential public disclosure with inventors. Unfortunately, a fair amount of empirical study may be required to find out just how quickly an on-line journal will post material from an upcoming issue. One notable exception is Blood Cells, Molecules & Diseases, which informs researchers in its "Instructions to Authors" about the relative timing of Internet and paper publication. The journal also includes the Internet posting date on each paper article as the official date of publication. According to Dr. Ernest Beutler, the editor-in-chief of Blood Cells, Molecules & Diseases, the reason that his journal "adopted the practice of accurately dating all of our articles is precisely to establish priorities both from the point of view of scientific credit and from the point of view of establishing a date of dissemination of the intellectual property."

As a practical matter, it should be helpful to discuss the risk to patent rights posed by electronic publication with inventors, and perhaps to solicit their aid in lobbying publishers of on-line journals to follow the full disclosure policy of Blood Cells, Molecules & Diseases. Such discussion would also serve as a reminder to inventors that, under patent law, "publication" means that information becomes publicly accessible regardless of the form of the information.

A Letter to AUTM

Dear Fellow AUTM Members:

For those of us who knew and loved Raymond H. Kahn, Ph.D., his passing on July 5, 1996, at the age of 69 was a very sad day. There are not sufficient words in the language to do justice to the impact this man had on the world around him or to describe the loss that so many people have suffered with his passing. Ray's passionate integrity was an inspiration to many of us that knew him. In this world focused on success or failure, Ray Kahn's consistent conduct reminded all of us that honesty and courtesy sow seeds of respect and friendship that are returned many times.

Raymond Kahn was born on August 29, 1926, in New York City. After serving in the US Navy during World War II, he received his bachelor's degree from the University of California at Los Angeles in 1948. He pursued graduate study at the University of California at Berkeley, where he conducted research on the structure and function of the mammalian reproductive system. Ray received his master's degree from Berkeley in 1949 and his doctoral degree in 1953. He spent one year as an Ameri-

can Cancer Society Fellow conducting post-doctoral research in the laboratory of Dame Honor B. Fell in Cambridge, England. Ray returned to the US to become an Assistant Professor at the University of Michigan Medical School. Over the next 25 years, he pursued a distinguished academic and research career, rising to the rank of Full Professor of Anatomy. From 1977 to 1982, Ray was Director of Research at Detroit's Henry Ford Hospital.

Dr. Kahn was appointed as Assistant Director of The Scripps Research Institute in 1982. He subsequently served as Associate Director, Administration, from 1983 to 1987, and as Industrial Liaison Officer until 1992. Ray retired in 1992 to devote his full time to consulting and the development of fledgling biotechnology companies. Dr. Kahn subsequently served as Chairman of the Board of Torrey Pines Institute for Molecular Studies, a company he helped found in 1988, President of Biotech Consult, Inc., and President of Desmos, Inc., another company he helped found.

Along with his active participation in AUTM, Ray was an enthusiastic member of LES, serving as the San Diego chapter liaison, and was also involved with the UCSD CONNECT program, the Endocrine Society, the National Council of University Research Administration and the local Harvard Business School Alumni Club.

Ray is survived by his wife, Judith, two daughters and a son, and three grandchildren. His family has set up a fund in his memory and has requested donations be designated for lymphoma research at the Scripps Research Institute, Attention Denise Scalzo, Dr. Raymond Kahn Memorial, 10666 N. Torrey Pines Rd., TPC-2, La Jolla, CA 92037. He will be missed.

Charlotte P. Clark
Desmos, Inc.

Michael T. White, Ph.D.
Myelos Neurosciences, Inc.

Advanced Topics Program Announcement

The 1996 Advanced Topics in Licensing Course- December 12 through 15 at the Arizona Biltmore, Phoenix- is a chance for our experienced members to sharpen their skills and participate in a lively, interactive forum on topics on the cutting edge of university technology transfer. Topics this year are on the theme of "value" and cover the spectrum from valuing your technology, to valuing your program's contribution to your institution, to valuing our collective contribution to the public good.

Thursday, 12/12, 1-7 PM: Technology Valuation: Rules For The Road. Practical applications of intellectual property valuation methods as used by university and industry technology managers and venture capitalists.

Friday, 12/13, 8:30 AM-noon; 5-8 PM: Adding And Calculating Value. Prototype development; the virtual company model of adding value; calculating induced investment and fair market value of equity; managing congressional and public perception of the value of university technology transfer.

Saturday, 12/14, 8:30 AM-4 PM: Communicating Value. AUTM survey- what it measures; communicating with faculty and administration; communicating with legislators; benefits of technology transfer to Canada.

Sunday, 12/15, 8:30 AM-noon: Valuing What We Do. Incentive compensation programs for university technology managers; valuing our work.

Make your plans now to join us for a great meeting and a chance to relax in the sun. Save an additional 10% on the early registration fee if paid before October 1, 1996; email (autm@ix.netcom.com), call (203-845-9015), or fax (203-847-1304) AUTM Headquarters Office for registration and hotel information.

Washington Update

by Janna Tom, University of California

August is the time for vacations, campaigning and Congressional recess, but certainly not time for rest for the legislative weary! There are several "moving target" patent-related bills that AUTM members should carefully watch now and over the next year or more!

Patent Reform Legislation

Early in this Congress, Rep. Dana Rohrabacher (R-CA) introduced HR 359 in response to the change in patent term created by the General Agreement on Trade and Tariffs (GATT) legislation. HR 359 proposes a patent term that is the longer of twenty years from date of earliest filing of the patent application or seventeen years from the date of patent issuance.

Introduced by Rep. Carlos Moorhead, HR 3460 is an omnibus bill that combines several other patent-related bills he had introduced previously in this session of Congress. Issues addressed by HR 3460 include: establishment of the US Patent and Trademark Office (PTO) as a Government corporation, early publication of patent applications, extension of patent term due to certain administrative delays, prior user rights, inventor protection, patent reexamination reform and other miscellaneous provisions.

You may recall the recent rumors that HR 359 and HR 3460 were considered dead for this Congress. That may

not be so! According to the Coalition to Preserve Patent Law Reform, an industry lobbying group, HR 3460 is not dead; that's the bad news. The good news is that the Coalition is interested in working with the university community, trying to understand our concerns, and finding some common ground that would ensure passage of the Moorhead bill. Universities interested in participating in this effort should contact Janna Tom at Janna.Tom@ucop.edu or 510-748-6624.

The Senate companion bill similar to HR 3460 is S 1961 (Hatch) which also includes melding the Copyright Office with the PTO into a new government corporation called the U.S. Intellectual Property Organization- a controversial issue among librarians and other copyright gurus. Although HR 3460 may be pushed to passage in the House, it is unlikely in the short time remaining in this Congress that S 1961 can be passed in the Senate, but more unlikely things have happened before, so we remain vigilent.

Other Patent-Related Legislation

Do you remember HR 1127 (Ganske) that would prevent issuance of a patent for medical and surgical procedures, administering medical or surgical therapy, or making a medical diagnosis unless that method is performed by or as a necessary component of a machine, manufacture, or composition of matter and claimed in the same patent for such machine, manufacture, or composition of matter? William D. Noonan, M.D., J.D., wrote an article in the December 1995 Newsletter about the issues prompting this legislation and presented further information at a plenary session at the 1996 Annual Meeting in Charleston. The senate companion bill, S 1334 (Frist), took a slightly different approach by allowing patentability of a medical or surgical procedure, but preventing patients, physicians, licensed health care practitioners and their affiliated institutions from being sued for infringement if they used a patented method for performing a medical or surgical procedure or making a medical diagnosis. As an alternative to the legislative bills, the PTO conducted hearings on May 2, 1996 to explore administrative solutions to this problem. There was little interest in and representation at the PTO hearings.

The issue has now resurfaced in HR 3814 (Rogers), the FY 1997 appropriations bill for the PTO (in addition to other agencies). On July 24, 1996, Rep. Ganske (R-IA) introduced an amendment that would prevent any funding by the PTO to issue patents for "any invention or discovery of a technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis" with some exceptions. The exceptions are:

-a patent for a machine, manufacture, or composition of matter, or improvement thereof, that is itself patentable subject matter, and the technique, method, or process referred to above is performed by or is a necessary component of the machine, manufacture, or composition of matter; or

-(a) a patent for a new use of or a new indication for a drug, new drug, or biologic product (all as defined in applicable statutes or regulation) that is not itself patentable subject matter; and (b) the effect of such drug, new drug, or biologic product on the body part on which it is used in the claimed method was not previously known or obvious to a person of ordinary skill in the art.

This amendment passed the House on the same day, but is not yet included in the Senate version of this bill. There is still an opportunity for this amendment to be incorporated into the bill on the Senate floor when Congress reconvenes in September 20.

And there is more to HR 3814! Several amendments on the House floor diverted approximately $54 million of funding from the PTO to Public Broadcasting ($5 million), Legal Services Corporation ($34 million), and other activities ($15 million.) Funding for the PTO in the approved FY 1997 House bill currently stands at $61.2 million which is the same level recommended by the Senate appropriations committee. Funding for the PTO in FY 1996 was approximately $82 million.

Commerce Report: Effective Partnering

As was described in the June 1996 Newsletter, the Department of Commerce Report issued a report entitled "Effective Partnering, A Report to Congress on Federal Technology Partnerships" which was discussed at a subsequent congressional briefing. Below is the July 18, 1996, letter from AUTM President Teri Willey addressed to Under Secretary for Technology Mary L. Good in response to the report.

If you have any comments about the above activities, the Government Affairs Committee welcomes your comments through the AUTM Government Resources, Regulations and Legislation Web site or directly to the Chair, Janna Tom, at 510-748-6624 or Janna.Tom@ucop.edu.

July 18th 1996

The Honorable Mary L. Good
Under Secretary for Technology
US Department of Commerce
Washington, DC 20232-0001

Dear Dr. Good:

The report to Congress on Federal Technology Partner-

ships, released May 14, 1996, speaks well of the Administration's efforts to promote government-industry partnerships and has many excellent recommendations. In common with Administration efforts, those of AUTM are very much focused on finding and implementing mechanisms to enhance industry collaborations with not-for-profit research institutions, in order to assure federally funded research results are commercialized and made available to the public. In principle we support your leadership to enhance public/private technology partnerships.

Since the briefing in May, leaders of our organization have met and thoughtfully considered your report and your comments during the briefing expressing the support by the Department of Commerce for the Bayh-Dole Act. We also considered the comments from your panelists, especially Dr. Robert White, regarding the role of universities in technology based innovation and the role they do play in ATP efforts. We very much appreciate these comments.

However, we are still concerned. Our concerts rest primarily with the practical implications of increased use of "exceptional circumstances." AUTM members, as practitioners and deal makers, are willing to concede that a case could be made to invoke "exceptional circumstances," in a very few situations, to improve the chances of technology being developed. But too often policies which make sense in a few situations are applied broadly- to situations where their effect is actually negative. Thus, we worry that encouraging the use of "exceptional circumstances" may inadvertently weaken an important link in the innovation chain and undermine the demonstrated effectiveness of the Bayh-Dole Act.

Although universities are not always the primary players in technology development and commercialization, universities and other academic research institutions are a critical link in the innovation chain. Our outstanding record in innovation is due to good legislation like the Bayh-Dole Act which offers mechanisms and incentives to go beyond traditional academic pursuits by developing relationships with industry and thereby optimizing the use of public resources by bringing, publicly funded inventions to the public.

Over the last decade the men and women of the AUTM organization have made a significant contribution to the effective transfer of technology from the research laboratory to the industrial production line by adapting methodologies that work. If there are situations in which use of "exceptional circumstances" will accomplish the goals of technology commercialization by placing ownership of government-funded university inventions with government or a government-assignee, we will support it to the extent it works better that the proven Bayh-Dole practice of permitting the university to retain title. Where the use of "exceptional circumstances" has a counterproductive effect, we will continue to oppose its use as contradictory to the intent of Congress as expressed in passing the Bayh-Dole Act in 1980.

While we may have differences in our perceptions of the role the not-for-profit research community plays on the continuum of technology development and commercialization, we both work toward the success of US industry. In that spirit, please accept the AUTM organization as a resource to the Department of Commerce as you consider these important policy and practical issues. We would like to be part of the solution and to support the Department in it efforts to enhance technology development and commercialization.

Sincerely, Teri F. Willey, President

The Book Review

by Katherine L. Chapman, University of Texas Southwestern Medical Center, Dallas

The subtitle of this book caught my eye: The Coming American Renaissance: How to Benefit from America's Economic Resurgence, by Michael Moynihan, Simon & Schuster, $23. Certainly an topic that would interest AUTM members, but for twenty-three dollars?

Michael Moynihan is policy adviser in the US Treasury Department, as well as technical adviser for the Department of Commerce (and nephew of Senator Daniel Patrick Moynihan). He has written a serious if not scholarly book on the expectations for the US economy. In it, he dares to make predictions about which areas of the country will thrive economically and what types of technologies and businesses are going to be successful. Mr. Moynihan notes the origin of American's current pessimism about the economy began in the 70's and 80's and describes the US as "a nation of Eeyores . . . Like Winnie the Pooh's pessimistic companion, we view every cloud as a sign of rain and every pot of honey as beyond our reach."

Without hesitation, Mr. Moynihan optimistically explains that the economy has changed course, and is now on a brighter path, which will result in the American Renaissance of his book's title. Surprising to the non-economist, Mr. Moynihan does not fear the deficit, which he says is one-eighteenth of the size it was right after World War II. He does not see dark clouds in the level of taxes or expenditures for social services, which he states are relatively low. Even the Social Security system he believes will survive. He even believes the corporate downsizing has created a "more dynamic, adaptable economy," contributing to the growth in the number of small businesses. Talk about optimism!

Frankly, I found this book a relief after hearing the fatalistic pedagogues disparage the American economy and workers. While I do not have the wisdom or experience to say if Mr. Moynihan is right or wrong about our economy, I did enjoy having the opportunity to read a different view, and one written by someone with his credentials and reputation. I recommend this book to AUTM members. At the least having read it, you will be able to hold your own in a conversation about the future of the US economy, and better form your own opinion about what the future may hold for the economy and technology transfer.

Of Note ...

AUTM Is Looking For A Few Good Women And Men As technology transfer and related functions increase in visibility and importance, other professional and scientific organizations are becoming involved in "our" issues. As the largest organization representing non-profit technology transfer professionals, AUTM believes it is important to identify and reach out to these other organizations and professionals and offer AUTM as a resource. The Outside Organizations Committee needs your help in two ways: 1) to identify these organizations and the individuals within them involved in technology transfer issues; and 2) to compile a roster of AUTM members who are active in these organizations and who are willing to serve as liaisons. Please e-mail the names of any such organizations with which you are involved and whether you have an interest in working on this outreach effort, to Kathleen Denis at: denis@allegheny.edu. The Committee would like to have these organization and liaison lists assembled by the Annual Meeting. Thanks!

Basic Licensing and TOOLS Courses The Basic Licensing and Technology Operations and Organization Licensing Skills (TOOLS) Courses will be held simultaneously at the Hyatt Regency-Capitol Hill Hotel, Washington, DC, October 27-30, 1996. The new TOOLS Track will cover office administration issues and will provide the attendees with a good understanding of the importance of all of the many forms, reports, and data entry associated with a busy technology transfer office and tips on how to improve their systems. It's not too late to register by contacting AUTM Headquarters Office by email (autm@ix.netcom.com), phone (203-845-9015), or fax (203-847-1304).

Members of AUTM are encouraged to contribute items for this *Newsletter* to Chris Dippel, Technology Transfer Office, Children's Hospital, 300 Longwood Avenue, Boston, MA 02115 (Phone 617-355-7050, Fax 617-232-7485).

Association of University
Technology Managers
49 East Avenue
Norwalk, CT 06851-4903

NIH PROCEDURES FOR HANDLING NON-ELECTION OF TITLE TO PATENTABLE BIOLOGICAL MATERIALS

NIH GUIDE, Volume 25, Number 16, May 17, 1996

P.T. 36; K.W. 0780010, 1014006

National Institutes of Health

A. Purpose

This notice sets forth the National Institutes of Health (NIH) policy for allowing contractors and grantees (hereafter "Contractor") to license biological materials on which the contractor elects not to file a patent application and which are submitted to the NIH for review and possible election of government title under the Bayh-Dole Act.

B. Background

The NIH Office of Technology Transfer (OTT) has been delegated the authority to elect title to extramural inventions on behalf of the NIH. Under the Bayh-Dole Act, the NIH Contractor may elect title to inventions developed with NIH funding, but must file a patent application within one year of such election. Where the Contractor elects not to file a patent application, the Government may request title. Typically, the Contractor's election not to file a patent application on an invention is an indication that the Contractor is not interested in retaining domain over the invention.

However, this is not necessarily the case with regard to patentable biological materials, which may frequently be licensed for commercial use without patent protection. The policy and procedures established by this notice are intended to simplify: (1) the reporting by Contractors of their intention to not file a patent application on the invention but to license the tangible biological material; and (2) the non-election of title to these inventions by the Federal Government where certain terms and conditions are met.

C. Policy

It is the policy of the United States Public Health Service (PHS) to make available to the public the results and accomplishments of the activities it funds. Restricted availability of unique research resources, upon which further studies are dependent, can impede the advancement of research and delivery of medical care. A notice in the NIH Guide for Grants and Contracts (Vol. 23, No. 26, July 15, 1994) and the PHS Grants Policy Statement explain in full PHS policy with regard to the distribution of research resources developed with PHS funds.

The NIH Guide notice referenced above and the PHS Grants Policy Statement also set forth PHS policy encouraging the commercialization of the products of research developed with PHS funding, and allow institutions to make materials available to others for commercial purposes with appropriate restrictions and licensing terms. To ensure consistency with its public availability goals, the NIH Guide notice (referenced above) and the PHS Grants Policy Statement require that where the product of research developed with federal funding is a patentable, but unpatented, research product, the terms of a license must be no more restrictive than they would have been if the product had been patented.

Accordingly, where the Contractor agrees with the conditions set forth below, which ensure the availability of unique research resources, NIH will not request title to the subject invention and will

grant a Contractor's request to distribute the unpatented, tangible material through licensing.

D. Procedures

A contractor electing title to patentable biological materials and requesting to distribute them through licensing as unpatented tangible research materials must agree to the following conditions:

1. The Contractor must make a written request to the Division of Extramural Inventions and Technology Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7750, Bethesda, MD 20814-7750

2. Information describing the invention must be made publicly available either through publication in the scientific literature or by other appropriate means;

3. The licensing strategy must ensure that the research resource will be made available to the nonprofit research community. Generally, this can be accomplished through nonexclusive licensing, or exclusive licensing for distribution or sale of the materials. If an exclusive license is negotiated for internal use by a for-profit entity, the license must address continuing availability of the material to the nonprofit research community. Any exclusive license must provide for conversion to nonexclusive status or termination of licensee's rights upon failure to comply with the terms addressing continuing availability;

4. If an exclusive license is executed, provision must be made for independent maintenance of the material, such as at a national repository, or the originating grantee laboratory;

5. The government shall have a worldwide, irrevocable, unlimited royalty free, paid-up license in the material to make, use or distribute, or to have it made, used, or distributed for the Government. Upon request, sufficient quantities of the biological material shall be provided to the Government with such documentation as the Government is needed to preserve, use, and replicate the material to meet PHS needs; and

6. If the Contractor fails to fulfill the conditions of paragraphs 1-4 above, NIH shall automatically have the right to: (1) distribute the material, or (2) require the Contractor to comply with the Unique Research Resource requirements of its grant.

F. Effective Date

The policies and procedures set forth in this notice are effective immediately.

INQUIRIES

For additional information on this notice, contact:

Ms. Sue Ohata
Division of Extramural Inventions and Technology Resources
National Institutes of Health
6701 Rockledge Drive MSC 7750
Bethesda, MD 20892-7750
Telephone: (301) 435-1986
FAX: (301) 480-0272
Email: Sue_Ohata@nih.gov

AUTM Calendar

Association of University Technology Managers, Inc. *Version 9/1/96*

OCTOBER 1996	NOVEMBER 1996	DECEMBER 1996
26: AUTM Board of Trustees Meeting, Hyatt Regency Capitol Hill, Washington, DC 27-30: Basic Licensing/TOOLS Course, Hyatt Regency Capitol Hill, Washington, DC	15: ***AUTM NEWSLETTER*** Articles Due	11-15: Advanced Topics in Licensing, Arizona Biltmore Hotel, Phoenix, AZ 30: December ***AUTM Newsletter*** Published 30: *AUTM JOURNAL* (tent)
JANUARY 1997	**FEBRUARY 1997**	**MARCH 1997**
31: Publication of AUTM Licensing Survey Data for Fiscal Year 1995	15: ***AUTM NEWSLETTER*** Articles Due 19: AUTM Board of Trustees Meeting, San Franciso, CA 19-23 AUTM 1997 Annual Meeting, The Fairmont Hotel, San Francisco, CA	30: March ***AUTM NEWSLETTER*** Published
APRIL 1997	**MAY 1997**	**JUNE 1997**
15: 1997 AUTM Licensing Survey Forms Distributed	15: ***AUTM NEWSLETTER*** Articles Due 15: ***AUTM JOURNAL*** Articles Due	29-7/2 Eastern Region Meeting, Holiday Inn by the Bay, Portland, Maine 30: June ***AUTM NEWSLETTER*** Published
JULY 1997	**AUGUST 1997**	**SEPTEMBER 1997**
	2-5 Central Region Meeting, Campus Inn, Ann Arbor, Michigan	

(continued on reverse ...)

AUTM 1996/1997 Calendar Detail

Version: 9/1/96 *Association of University Technology Managers, Inc.*

DATE	DESCRIPTION	CONTACT NAME AND NUMBER
11/15/96	AUTM Newsletter Articles Due ... submit to Chris Dippel, Technology Transfer Office, Children's Hospital, 300 Longwood Avenue, Boston, MA 02115	Chris Dippel Ph: 617-735-7050 Fx: 617-232-7485
12/11-15/96	AUTM Advanced Topics in Licensing, Arizona Biltmore Hotel, Phoenix, Arizona ... the final program will be released to all members shortly and a copy will be included on the AUTM web site.	Penny Dalziel Ph: 203-845-9015 Fx: 203-847-1304 autm@ix.netcom.com
12/30/96	AUTM Journal Articles Due ... Original, unpublished manuscripts on any aspect of the management of technology and intellectual property should be submitted to Trice Bryan, Editor, AUTM Journal, or Jean Mahoney, AUTM VP/Communications. Papers will be reviewed by the Editorial Board and other designated reviewers. Prospective authors are requested to submit an original and two copies, printed double-spaced, with consecutively numbered pages. The cover page should have the title, author, affiliation, and mailing address. A brief abstract of 100-200 words should preface the manuscript, and a short statement about the author's position and experience should be included.	Trice Bryan University of California Office of Tech Transfer 1320 Harbor Bay Parkway Alameda, CA 94502 Ph: 510-748-6616 Fx: 510-748-6639 Jean Mahoney Princeton University Tech & Tradem. Licens Post Office Box 36 Princeton, NJ 08544-0036 Ph: 609-258-3097 Fx: 609-258-1159
2/15/97	AUTM Newsletter Articles Due ... refer to 11/15/96 above	Chris Dippel Ph: 617-735-7050 Fx: 617-232-7485
2/19/97	AUTM 1997 Annual Meeting ... full program and registration information will be mailed to all members on November 1, 1996. The program will also be included on the web site.	Penny Dalziel Ph: 203-845-9015 Fx: 203-847-1304 autm@ix.netcom.com
5/15/97	AUTM Newsletter Articles Due ... refer to 11/15/96 above	Chris Dippel Ph: 617-735-7050 Fx: 617-232-7485