PROGRAM

Issues of Interest to Universities, Non-Profits and the Pharmaceutical Industry

December 12, 2003

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Legislative Issues of Interest to Universities, Non-Profits and the Pharmaceutical Industry

December 12, 2003

11:50 a.m.	Opening Remarks: Michael Remington
11:55 a.m.	Self-introduction of participants and their organizations
12:00 noon	Helen Rhee, PhRMA "Medicare Reform: Hatch-Waxman Act amendments, reimportation"
12:20 p.m.	Lunch Served (Buffet Style)
12:30 p.m.	Sheldon Steinbach, ACE, "The Joint Committee of the Entertainment and Educational Communities: Lessons for the Technology Transfer Industries"
12:45 p.m.	"2004 Forecast": PhRMA Perspective
1:00 p.m.	"2004 Forecast": University Perspective
1:15 p.m.	Bayh-Dole Act Birthday Cake
1:30 p.m.	Technology Transfer: What Should be Done to be More Responsive to Policy-Makers? Pat Harsche/Jon Soderstrom
1:45 p.m.	Closing Remarks: Valerie Volpe "Where Do We Go From Here?": Regional conferences, Hill briefings, media, cross-fertilization

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PhRMA/UNIVERSITY WORKING GROUP

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DECEMBER 12, 2003 MEETING

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C

MEMORANDUM

TO: Meeting Participants

FROM: Chris Wilson
Michael J. Remington

DATE: April 4, 2003

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

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Public policy and governmental relations representatives of various university, technology transfer and medical research associations and one university foundation as well as representatives of the Pharmaceutical Research and Manufacturers Association (PhRMA) met on February 27, 2003 at 11:30 a.m. at Savino's Cafe in Washington, D.C. The purpose of the meeting was twofold: (1) for the attendees to get to reacquainted since September's meeting; and (2) to discuss the current public policy proposals and legal movements affecting the pharmaceutical industry and the university community both domestically and internationally and their negative impact on the Bayh-Dole Act. In doing so, participants hoped to share the policy goals and prerogatives of their respective organizations in an attempt to find common ground.

Present at the luncheon meeting were the following:

- Sheldon Steinbach, Esq., Vice President and General Counsel, American Council on Education (ACE)
- Richard Harpel, Director, Federal Relations-Higher Education, National Association of State Universities and Land-Grant Colleges (NASULGC)
- Robert Hardy, Associate Director, Council on Governmental Relations (COGR)
- Richard J. Turman, Director of Federal Relations, Association of American Universities (AAU)
- Michael J. Remington, Esq., Drinker Biddle & Reath LLP
- Christopher E. Wilson, Government Affairs Specialist, Drinker Biddle & Reath LLP
- Stephen Heinig, Senior Staff Associate, Division for Biomedical and Health Sciences Research, Association of American Medical Colleges (AAMC)
- Andy Cohn, Director of Public and Governmental Relations, Wisconsin Alumni Research Foundation (WARF)
- Norman J. Latker, Esq., Browdy & Niemark
- Patricia Harsche, Vice President, Planning and Business Development, Fox Chase Cancer Center; President, Association of University Technology Managers (AUTM)
- Valerie Volpe, Senior Director-Alliance Development, PhRMA

- Bruce Kuhlik, Senior Vice President & General Counsel, PhRMA
- Sean Darragh, Deputy Vice President, International Policy, PhRMA
- Erika King, Assistant General Counsel, PhRMA

OPENING REMARKS

Shelley Steinbach welcomed all participants and noted that there is an "interesting" array of issues to be discussed among meeting participants. Specifically, Shelley mentioned the growing animal rights movement as a problem that both the university and the pharmaceutical communities must face. He also referred to the notebooks that we provided to meeting participants. Stating that "no one gets anything done in D.C. alone," Steinbach emphasized the need for all participants to remain in contact after the meeting when issues arise. Following Shelley's opening remarks, he invited participants to give brief self-introductions.

OPENING PRESENTATIONS

Bruce Kuhlik: "Current State of Play: Hatch-Waxman Act

Bruce Kuhlik began the discussion with a brief overview of what transpired last year in Congress with regard to patent law. Specifically, Bruce mentioned S. 812, which passed the Senate, as a bill PhRMA opposed vehemently and noted that it was "bad policy" all around. He said PhRMA was pleased that the bill never became law.

Bruce went on to recall PhRMA's astonishment when the President on October 21, 2002 announced from the Rose Garden a proposed new rule-making at the FDA concerning patent law. Kuhlik stated that the new rule does two things: 1) it restricts the types of patents listed in the Orange Book; and 2) it provides just one 30-month stay during a patent litigation proceeding. According to Bruce, PhRMA companies looked at the proposed rule and decided they could live with it, provided some "tweaking" occurred. Additionally, Bruce acknowledged that whatever faults the rule may have, they were not as severe as those present in S. 812.

Bruce stated that the final rule will be issued by late March or early April 2003 and that pertinent congressional hearings can be expected to follow soon thereafter. He was asked to provide copies of the comments submitted by PhRMA to the FDA during the rulemaking process to the meeting participants. [After the meeting, he did so electronically. Mike Remington forwarded these materials to all participants for insertion in their notebooks.]

Robert Hardy noted that COGR's review of the proposed rules revealed that the "takings" aspect of previous patent law reform proposals was not present and that COGR was pleased that was so. Bruce added that the new rule should put universities "in good stead" as regular patent enforcement tools will remain in place.

Andy Cohn inquired as to what "technical" concerns PhRMA had with the proposed rules. Bruce noted that an unintended consequence of the rules would allow generic drug

companies to "play games" with patent certifications. PhRMA offered guidance in its comments that would quash that possibility.

[After the meeting, Bruce also provided a memo summarizing public comments on the FDA's NPRM, a summary of FDA's proposed regulations, and a chart on the "Generic Industry Flip-Flop."]

Andy Cohn and Pat Harsche: "Technology Transfer—University Priorities"

Pat Harsche and Andy Cohn discussed the priorities of universities. Harsche opened by providing a brief history of AUTM, noting that its 30th anniversary is near. Consisting of 3200 members from 34 countries, AUTM has a "diverse" membership, though its diversity makes it difficult for AUTM to take a unified position on any given issue. Pat made special note of AUTM's website, www.autm.net, as a valuable resource of information on technology transfer issues. She also stated that AUTM has just revised its technology transfer manual and that it should be available soon through the website.

Richard Turman noted that he relies on Pat and AUTM a great deal, especially as a communications tool. In that vein, Mike Remington inquired whether AUTM could communicate at the state level (because public policy issues arise there too). Pat Harsche said that AUTM has the ability to communicate with its members state-by-state and it plans to create a committee in each state.

Andy Cohn stated that he was a member of AUTM's new public policy committee. He added that he is "more than a little disturbed" by the number of attacks on Bayh-Dole. Andy made it clear to all present that Bayh-Dole "must be preserved" as the legislation "revolutionized" technology transfer. Secondly, Andy stated that he has concerns about the *Bristol-Myers* case that created a gaping exception for pharmaceutical companies that seek FDA approvals to conduct research on university-held patents. Andy also raised the Federal Circuit decision issued in 2002 in *Madey v. Duke University* in which the court denied the experimental use exemption in the patent law to all academic scientific research, even when that research is manifestly noncommercial. Lastly, Andy made all meeting participants aware that WARF (with support from ACE and NASULGC) is working on a collaborative research bill to be introduced, hopefully, this session of Congress.

Shelley Steinbach asked if there is any opposition to the collaborative research bill. Both Andy and Mike Remington stated that there is some opposition, particularly from some patent lawyers and the American Intellectual Property Law Association. Richard Harpel noted that there is a great deal more recognition on Capitol Hill that intellectual property is a "big deal" to universities, but that could be a double-edged sword as Members can both support your efforts and also threaten to thwart your prerogatives.

Sean Darragh: "Patents and the International Situation"

Sean Darragh prefaced his presentation by acknowledging that patent rights in the global arena are not hanging by a hair; rather they are hanging by a "split end." Sean provided the

participants with an overview of the evolution of the debate on patents as it has occurred globally. Sean noted that the debate traces itself back to the emergence of the HIV/AIDS epidemic in Africa. This epidemic brought a great deal of attention on the fact that poor, underdeveloped countries simply could not afford to purchase the medicines necessary to abate the spread of the disease. Immediately, the public perception was forged that pharmaceutical companies were greedy, uncaring and unwilling to help. However, according to Sean, the public perception is wrong as 95% of all drugs being used in Africa are not covered under patent law. Admittedly, according to Sean, PhRMA did not handle the public affairs situation well.

Sean explained that there is global movement, led by China and India, to eviscerate the entire patent system. Despite concessions made by the U.S. in the DOHA Round of trade talks providing for a moratorium on patent prosecutions with regard to certain medicines in poor countries, there is a cry for patents to be lifted on all medical devices too, not just medicines. PhRMA worked with the Biotechnology Industry Association (BIO) to ensure that further expansion of a moratorium did not take place.

Sean stated that PhRMA is happy with the initial moratorium agreement as well as with the President's policy announcement made in the course of his State of the Union address asking for $15 billion to fight AIDS in Africa.

Concerns were raised by several meeting participants that a moratorium would lead to the flooding of the market with cheap generic drugs. Sean responded that no flooding would take place as there is not enough money to be made in the developing world to necessitate heavy investment there.

Other participants were curious as to how the U.S. enforces patent agreements and punishes violators overseas. Both Sean Darragh and Mike Remington pointed out that a country with an ineffective and inadequate patent law could be hit with trade sanctions in the form of tariffs on products that the offending country exports to the U.S. The USTR also keeps a "special 301" list for countries with records of inadequate intellectual property laws.

In terms of the academic community's viewpoint on international patent law, Shelley Steinbach noted that the community is just getting its feet wet in the WTO. He said that it is vitally important, as much of the university community's research is marketed overseas, that the community create a presence in the international arena.

Richard Turman: "Animal Terrorism and Legal Rights for Animals"

Richard Turman opened his presentation by offering to host the next luncheon meeting, perhaps at AAU's office in Washington, D.C.

Richard stated that there is a visible need for universities to engage with PhRMA on animal rights issues, especially as the level of attention to the issues rises in the media and as the level of violence inflicted upon researchers increases. Valerie Volpe concurred with Richard and offered to create an opportunity for him or someone else from the academic community to brief the pertinent PhRMA personnel on the issues. Richard welcomed the suggestion.

Richard elaborated further on the "large and growing" movement to provide legal rights to animals. Specifically, he said that there is a move towards the creation of case law and that some consider animal rights to be the next generation of civil rights. Richard mentioned a proposal being formulated by the New York City Bar Association and the ABA that would extend some guardianship rights to animals. If the resolution passes the City Council, it is possible, according to Turman, that the ABA would seek Congressional approval as well.

Shelley noted that the animal rights issue will "keep us [meeting participants] together for a long time." Pat Harsche agreed with Shelley and added that an entire generation of students are currently being educated under the premise that scientific research on animals is wrong. Thus, according to Pat, future researchers and younger ones today are less inclined to support the academic community in its fight to maintain the right to perform research on animals. Richard stated that Hill staffers, who are predominantly young, also are more inclined to support animal rights advocates.

Valerie Volpe: "The Bayh-Dole Act: Is It Under Political Attack and What Should Be Done?"

Valerie wrapped up the organized presentation period by acknowledging that those in support of current patent law are fighting a tough public relations war, especially when lives are at stake. To counter public sentiment on the side of those in favor of removing patent protections to assist the sick and dying, Valerie suggested that educational conferences are needed on a regional basis as well as in Washington, D.C. The premise of the conferences would be to highlight the important discoveries that have been made, and lives saved, by virtue of the patent protections inherent in the Bayh-Dole Act. Valerie finds it "unacceptable" that those who malign the Bayh-Dole Act have suffered no consequences for their actions. For her, it is time to start being proactive and not just reactive. In this regard, Valerie suggested the need for Hill briefings to educate a select number of members and staff. These briefings could be done individually or collectively.

INFORMAL DISCUSSION

Norm Latker offered his opinion with regard to the ongoing debate on the Bayh-Dole Act. Primarily, Norm stated that he finds it disheartening not to hear discussion about the principles underlying the Bayh-Dole Act. The guiding principle present during the creation of the Act was that production must come before distribution and that incentives must be in place for interested parties to partake in the research and development of medicines, according to Norm. Norm believes that the general public and some decision-makers do not understand the principles behind the Bayh-Dole Act and that educating those in the dark is vitally necessary.

Richard Turman agreed with Norm and noted that when he was on the Hill a couple of years ago with regard to a bill offered by Sen. Wyden he found himself having to educate many staffers on the basics of the Bayh-Dole Act. Additionally, he said that unless there is a threat of action on the Hill with regard to Bayh-Dole, few staffers are interested in learning the background and underlying principles of the Act. Richard suggested that the 23rd birthday of the

Act could serve as a valuable "hook" for supporters of the Bayh-Dole Act to engage and educate individuals on the benefits of the Act.

Rich Harpel echoed Richard Turman's frustration when interacting with Hill staffers on issues concerning the Bayh-Dole Act. Rich believes staffers are not grounded in the basic principles of the Act and, at times, he has found that some staffers incorrectly assume that research and development performed by virtue of the Act's protections is federally funded and, therefore, it belongs to the public.

Mike Remington stated that he "sort of panics" when he learns of hearings on the Hill with respect to the Bayh-Dole Act as he knows that there is a lot of misinformation floating around in the congressional offices. Because of this, Mike agreed with Valerie's recommendation for a proactive approach, stating that a good offense on the Hill acts as a good defense too. In that vein, Remington noted that a regional education conference in Wisconsin is expected to be set up in the near future. Funding assistance for the conference could come from an organization headed by former Patent Commissioner, Bruce Lehman. He could provide seed money to spearhead the effort. All participants acknowledged that a regional conference is needed and that additional ones should take place. Rich Harpel added that the assistance of state Centers of Excellence should be sought when coordinating a conference as the support of state governments would be helpful.

Andy Cohn suggested setting up a subcommittee that would be in charge of organizing the conferences. Pat Harsche suggested that it would be appropriate to hold a program during AUTM's 30th anniversary program in San Antonio, TX in the Spring of 2004 It was agreed by all meeting participants that a program should take place in conjunction with AUTM's San Antonio meeting. That conference could be a "grand finale" for the Bayh-Dole Act's 20th birthday (measured from the 1984 amendments). Richard Turman added that he would like at least one conference to take place in Washington, D.C. There seemed to be a consensus on that point too.

In closing, Shelley Steinbach thanked all for attending and stated that the meeting was productive. It was agreed by all present that further meetings should take place, but in the meantime additional discussion on the topics raised during this meeting should continue on an informal basis between individuals and organizations within the group.

SUMMARY OF CONSENSUS ITEMS

- Bruce Kuhlik would distribute to participate copies of PhRMA's comments submitted to the FDA during its rulemaking process on applications for FDA approval to market a new drug: Patent Listing Requirements. [This has already been done.]

- As regards, FDA and Hatch-Waxman reform, PhRMA will monitor regulatory and legislative developments and keep the group informed.

• Sean Darragh's prepared remarks would be distributed electronically to all participants pursuant to request.

• PhRMA will keep the group informed of international developments; individual group members and the organizations they represent may weigh-in (with letters to USTR Ambassador Robert Zoellick) as they deem appropriate.

• Educating elected officials, Hill staffers and the general public by way of conferences and public relations tools is imperative. At least one regional conference should take place in 2003 in Madison, Wisconsin, and perhaps another in Tennessee, California, or in Washington, D.C. Also during 2003, Hill briefings should be explored. Additionally, the parties should consider a 23rd birthday party celebration on December 12 for the Bayh-Dole Act, as enacted on December 12, 1980.

• Mike Remington and Andy Cohn are authorized to meet with Bruce Lehman about the Wisconsin regional conference.

• A "briefing" should take place between PhRMA and the university community with regards to terrorism and animal rights issues.

• Further informal meetings to discuss legislative and regulatory proposals that impact the pharmaceutical industry and universities should continue.

MEMORANDUM

TO: Meeting Participants

FROM: Chris Wilson
Michael J. Remington

DATE: September 30, 2002

RE: Luncheon Meeting Concerning the Bayh-Dole Act

Public policy and governmental relations representatives of various university and medical research associations and one university foundation as well as representatives of the Pharmaceutical Research and Manufacturers Association (PhRMA) met on September 26, 2002 at 11:30 a.m. at the Jefferson Hotel in Washington, D.C. The purpose of the meeting was twofold: (1) for the attendees to get to know each other better; and (2) to discuss the current legislative proposals affecting the pharmaceutical industry and the university community and their negative impact on the Bayh-Dole Act, and in doing so to share the policy goals and prerogatives of the participants' organizations in an attempt to find common ground.

Present at the luncheon meeting were the following:

- Sheldon Steinbach, Esq., Vice President and General Counsel, American Council on Education (ACE)
- Richard Harpel, Director, Federal Relations-Higher Education, National Association of State Universities and Land-Grant Colleges (NASULGC)
- Kate Phillips, President, Council on Governmental Relations (COGR)
- Robert Hardy, Associate Director, Council on Governmental Relations (COGR)
- Richard J. Turman, Director of Federal Relations, Association of American Universities (AAU)
- Michael J. Remington, Esq., Drinker Biddle & Reath LLP
- Christopher E. Wilson, Government Affairs Specialist, Drinker Biddle & Reath LLP
- Stephen Heinig, Senior Staff Associate, Division for Biomedical and Health Sciences Research, Association of American Medical Colleges (AAMC)
- Andy Cohn, Director of Public and Governmental Relations, Wisconsin Alumni Research Foundation (WARF)
- Norman J. Latker, Esq., Browdy & Niemark
- John T. Kelly, M.D., Ph.D., Senior Vice President, Scientific & Regulatory Affairs, PhRMA
- Valerie Volpe, Senior Director-Alliance Development, PhRMA
- Rachel Kerestes, Director of Policy, PhRMA
- Missy Jenkins, Senior Director, Federal Affairs, PhRMA

- Sara Radcliffe, Director, Science and Regulatory Affairs, PhRMA
- Gregory J. Glover, M.D., Esq., Ropes & Gray

OPENING REMARKS

Valerie Volpe welcomed all participants and provided a brief overview of her job duties and the priorities of PhRMA in forging working relationships with parties that share common interests. She additionally stated that PhRMA perceives the legislation proposed by Sens. McCain and Schumer (S. 812) and recently passed by the Senate, and House companion legislation (H.R. 5311), as a "threat" and that she hoped it could be discussed over the course of the meeting.

Dr. John Kelly echoed Valerie's remarks and additionally noted that collaboration between universities and the pharmaceutical industry is "critical" as "future progress is not ensured." Both Valerie and John made the fundamental point that pharmaceutical companies and universities engage in their respective activities to benefit the public (*e.g.*, the patient).

Lastly, Mike Remington welcomed all and made special note of Norm Latker's presence at the meeting by commenting on Norm's vast institutional memory regarding the creation of the Bayh-Dole Act. Mike also noted that a meeting agenda had been prepared to ensure a balanced and open exchange of the various perspectives.

OPENING PRESENTATION

As a foundation for discussion among the participants, Dr. Gregory Glover gave a Power Point presentation entitled: "Importance of Patents to the Discovery & Development of New Treatments & Cures." Greg's presentation consisted of a general overview of the pertinence of patent law to the research and development of pharmaceutical products by universities and the pharmaceutical industry. Additionally, he provided a specific discussion regarding the impact that the Bayh-Dole Act and the Hatch-Waxman Act have had on the development of health care products. Lastly, Greg outlined PhRMA's key concerns with regards to S. 812 and H.R. 5311, stating that the proposed legislation seeks to alter the spirit of the Bayh-Dole Act.

As a follow-up to Greg's discussion of S. 812 and H.R. 5311, Richard Harpel asked him whether or not the proposed legislation had any redeeming value or if the legislation should be "killed" outright. Greg, Missy Jenkins, Valerie Volpe and Rachel Kerestes all agreed the proposed legislation should be "killed" and that the two bills were solutions in search of a problem.

Upon completion of Greg's presentation, John suggested that it would be beneficial if Greg's Power Point presentation was converted to document form and distributed to all participants. All attendees agreed.

INFORMAL DISCUSSION

With Greg Glover's presentation stimulating questions regarding the Bayh-Dole Act and proposed legislative changes, the rest of the luncheon was devoted to an exchange of viewpoints among all participants regarding areas of mutual and exclusive interest. Participants also engaged in self introductions and described their respective organizations.

John Kelly opened the discussion by acknowledging that in today's political climate the issue of prescription drug "cost" weighs heavily on the minds of PhRMA and its member companies. Though university representatives recognized the importance of cost discussions to the political debate, they stated in general terms that "cost" issues were not their primary concern. However, to the extent that universities engage in less collaborative research, that is of concern to them.

Shelley Steinbach noted the importance of personal relationships in Washington, D.C., and sounded a refrain that meetings of this sort are extremely valuable. Shelley also recognized that joint meetings stimulated mutual understanding with the possibility of achieving joint positions.

As the discussion continued, Richard Turman made the point that the issue of "tech transfer" is important to his organization as it involves both research and government relations aspects. However, Richard cautioned that universities are "reluctant to get political."

Valerie Volpe argued that universities should be considering cost issues by noting that pharmaceutical companies will be reluctant to invest in research of drugs tailored for "boutique" diseases when there is a good chance that the companies will not recoup their investments.

Rich Harpel stated that the Bayh-Dole Act means different things to universities, but most importantly the Act provides an "environment of cooperation" between universities and pharmaceutical companies. It is for this reason that universities have an interest in preserving Bayh-Dole, according to Rich. Rich further stated that he has found that current Hill staff don't know much about the legislative intent of Bayh-Dole and that a lot of his time is spent "tutoring" Hill staff to some extent.

Kate Phillips also recognized the benefits of Bayh-Dole, but stated that the Council on Government Relations, is agency-focused, not Hill-focused. Nonetheless, she noted that she perceives "hostility" toward Bayh-Dole in many directions and that this hostility is troublesome. She made special mention of a "challenge" coming from Sen. Ron Wyden. Robert Hardy echoed Kate's statement and further added that it is essential from COGR's perspective to "preserve the central integrity of Bayh-Dole."

Andy Cohn mentioned three areas of concern for WARF that he hoped others will find common interest in: 1) collaborative research patent reform (a bill will soon be introduced in the U.S. House of Representatives); 2) sovereign immunity reform (which should not unnecessarily destroy state university patent rights); and 3) growing legal concerns regarding patent infringement issues and a broad research exception.

Rich Harpel noted that he and representatives from the NASULGC had "conversations" with Sen. Patrick Leahy and his staff regarding S. 2031, the sovereign immunity legislation. Rich found the dividing lines to be between the university community and the entertainment community. Further, he stated that he found the issue to be a conflict between state government and the federal government, thus it is a constitutional issue. According to Rich, the bill is on hold indefinitely, and that is good.

Upon hearing the concerns raised by participants, John Kelly acknowledged that there is "no lack of attacks" going on with regards to patent law and pharmaceutical research. He stated that "periodic" ongoing discussions could be helpful as it is in everyone's interest to weigh in with their concerns for all to hear. Attendees agreed.

In light of John's statement, Richard Turman stated two areas of common interest between universities and PhRMA, notably the doubling of funding for NIH and the use of animals for research.

Robert Hardy followed up by noting that he sees an "erosion" in NIH's commitment to Bayh-Dole and that NIH managers view Bayh-Dole as "more of an option" than before.

Mike Remington said that reorganization of the U.S. Patent and Trademark Office, especially with regards to fees, should also be a mutual concern for both universities and PhRMA. According to Mike, good government should be a shared goal. Attendees seemingly agreed.

Richard Turman stated that the university community is very concerned with "bias and patient safety issues." Further, he noted that presidents and chancellors are "keenly" aware and interested in human subject issues, another issue of mutual concern between universities and PhRMA companies.

Stephen Heinig said his primary interest is keeping information in the public domain. John Kelly agreed that that is an important concern, especially with regards to clinical trials. He then referenced a pamphlet handed out at the luncheon entitled " Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results."

Andy Cohn voiced a plea for mutual cooperation in the stem cell research debate. Valerie Volpe said that PhRMA is "not involved publicly yet" in the debate. However, she mentioned that PhRMA is supporting and funding individual member companies in their advocacy of the issue.

Aware of everyone's areas of interest, John Kelly acknowledged his amazement at how much commonality there was. He suggested that all parties should come together and celebrate the upcoming birthday of the Bayh-Dole Act amendments on December 12. All parties agreed that would be a beneficial thing.

Further, Mike Remington offered a suggestion that there should be an additional grass-roots approach to the celebration whereby individual companies and universities work together at the state and congressional district level in acknowledging the importance of the Bayh-Dole Act. That suggestion also received favorable acceptance.

In closing, it was agreed by all that patent law is necessary for the development of collaborative research between universities and pharmaceutical companies, to the betterment of the public. All attendees agreed that further meetings should occur, and that parties could approach each other directly on pressing issues of concern.

SUMMARY OF CONSENSUS ITEMS

- Dr. Glover's Power Point presentation would be distributed electronically to all participants.
- Informal meetings to discuss legislative proposals that impact on the pharmaceutical industry and universities are productive and should occur periodically.
- The "success" of the Bayh-Dole Act is critical to the future of collaborative research and the ability of universities and pharmaceutical companies to engage in inventive activities and to bring new products and processes to the market. However, because the Bayh-Dole is under criticism, its success should not be taken for granted.
- The parties should consider a 22nd birthday celebration on December 12 for the Bayh-Dole Act, as enacted on December 12, 1980.
- The parties should consider a grass-roots approach to Bayh-Dole programs to occur at a handful of universities where successful collaborative research and technology transfer have occurred.
- Patent law is necessary not only for inventive activities on university campuses and in pharmaceutical companies but also for collaborative activities between and amongst these entities. As a general proposition, legislative efforts to decrease patent protections should be seriously scrutinized by the respective parties which, based on their own priorities, should express opposition.

D

AIPLA Reports

A Periodic Notification of AIPLA Activities and
Current Developments in Intellectual Property Law

December 4, 2003

Legislative Developments

Generic Drug Amendments in Medicare Bill Are Cleared for White House

Included in the controversial Medicare legislation cleared for the White House November 25, 2003, are amendments to Title 21 and Title 35 that modify the patent enforcement mechanism as to generic drugs seeking pre-market approval by the Food and Drug Administration.

These provisions relate to the special infringement liability of generic drugs under 35 U.S.C. §271(e)(2). This provision creates infringement liability for a generic drug company that files with the FDA for premarket approval of a drug that is the subject of a patent listed in the FDA's *Orange Book*. The patentee is given 45 days from receiving the generic company's notice of the application to bring the Section 271(e)(1) suit.

Title XI of H.R. 1, entitled "Access to Affordable Pharmaceuticals," includes provisions that: (1) limit patentees to a single 30-month stay of FDA approval for a generic drug subjected to an infringement suit, to run concurrently with FDA consideration of the generic application; (2) give a drug applicant standing to bring a declaratory judgment action against a patentee that fails to sue under 35 U.S.C. 271 (e)(2) within the 45-day time limit; (3) give a drug applicant sued under Section 271(e)(2) the right to assert a counterclaim that challenges the relevant patent information listed in the FDA *Orange Book*; (4) allow damages determinations in infringement suits to consider the propriety of the *Orange Book* listings; and (5) forfeit the generic drug 180-day exclusivity period on evidence of an anti-competitive deal between the generic and patented drug companies.

Among the notable changes made to the legislation by the approved conference report are new conditions on the generic's right to seek a declaratory judgment absent an infringement suit. One change in particular addresses the concern that the bill originally attempted to legislatively create standing for the declaratory judgment action. A new Section 271(e)(5) states that under the right circumstances "the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed."

Another change is the elimination of an amendment to Section 287 of Title 35 which would have required the court to consider the propriety of the *Orange Book* listing in deciding whether to award the patentee treble damages.

To view the patent provisions of the conference report for H.R. 1, click here:
http://www.aipla.org/html/reports/2003/GenericDrugs.pdf

E

Joint Committee of the Higher Education and Entertainment Communities Technology Task Force

Note: This page is hosted by EDUCAUSE on behalf of the Joint Committee of the Higher Education and Entertainment Communities Technology Task Force

- Members of the Joint Committee and the Technology Task Force
- Joint Committee Review of Issues Press Release – September 2, 2003

REQUEST FOR INFORMATION #1

Technology Opportunities for Addressing Issues Associated with Peer-to-Peer File Sharing on the University and College Campus

- Press Release – April 28, 2003
- Text of the Request for Information
- Frequently Asked Questions
- Results of the RFI – Posted October 28, 2003
- File Sharing and P2P Issue Resources

ADDITIONAL RESOURCES

- Background Discussion of Copyright Law and Potential Liability for Students Engaged in P2P File Sharing on University Networks — A white paper discussing copyright law and P2P file sharing on university networks, prepared for the Joint Committee of the Higher Education and Entertainment Communities by a Washington, D.C., law firm.
- RespectCopyrights.org — A Web site developed by the Motion Picture Association of America

REQUEST FOR INFORMATION #2

Opportunities for Online Distribution of Music, Movies, and Other Digital Content on the University and College Campus

- Frequently Asked Questions
- Press Release – June 19, 2003
- Respondee Contact Information
- Text of the Request for Information

EDUCAUSE

Transforming Education Through Information Technologies

Joint Committee of the Higher Education and Entertainment Communities Members

Note: This page is hosted by EDUCAUSE on behalf of the Joint Committee of the Higher Education and Entertainment Communities Technology Task Force

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EDUCAUSE

Transforming Education Through Information Technologies

FOR IMMEDIATE RELEASE
The following release was issued by the [www.riaa.com] Recording Industry Association of America.

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Joint Higher Education and Entertainment Group Issues Review Of Year-Long Efforts To Curb Illegal File Sharing On College Campuses

A joint committee of leaders from the higher education and entertainment communities, formed to develop collaborative solutions to address illegal file sharing on college campuses, today released a review of its efforts and the progress accomplished during the past year, as well as projects still on the agenda.

The Joint Committee of the Higher Education and Entertainment Communities was formed last fall and is comprised of leaders representing universities, higher education organizations, and music and motion picture executives. The committee aims to provide a range of resources to school administrators in three basic areas: educational efforts (including practices surrounding the use of copyrighted works, student responsibility, and implications for peer-to-peer network file sharing), technological solutions (including computer network management technologies available to reduce illegal file sharing and the development of legal, campus-based music and movie/entertainment services), and examining differences and exploring prospects for collaboration on legislative initiatives.

"The collaborative efforts of higher education and the entertainment industry have already gone a long way toward addressing problems associated with the piracy of copyrighted material," said **Graham Spanier, president of Penn State University and co-chair of the Joint Committee**. "The progress in charting solutions and in awareness has been dramatic in recent months."

"The epidemic of illegal file sharing dramatically impacts both of our respective communities. We are in this boat together, and that's why collaborative solutions are the best approach," said **Cary Sherman, President, Recording Industry Association of America (RIAA) and co-chair of the Joint Committee**. "Within a short amount of time, there's been a sea change in the awareness of piracy's impact and the appreciation of the need to do something about it. The work of the Joint Committee deserves top-notch marks, but we still have much to accomplish."

"We are grateful to the university community who, under the leadership of Graham Spanier, has already made great inroads in addressing concerns about network abuse on campus. Our collaboration with the university community has yielded benefits to all parties involved," said **Jack Valenti, President and CEO of the Motion Picture Association of America (MPAA)**. "Only through a multi-pronged approach will the promise of the burgeoning digital era be fulfilled. Our industry is committed to providing consumers with the best possible viewing experience and the widest array of options by which they can be enjoyed. The Digital Future will benefit everyone: Computer makers, chip makers, consumer electronics manufacturers, and the creative community, but most of all it will benefit the American economy and millions of American families."

Among the group's specific projects:

- A Request for Information (RFI) about technologies offered by various companies that could help curb illegal peer-to-peer network file sharing on college and university campuses (http://www.educause.edu/issues/rfi/). The idea behind this RFI is to create a clearinghouse of readily-accessible information about technologies now available to reduce infringing use of P2P on campus networks, and a convenient and easy resource for school administrators to consult. That RFI was issued in April and the review is near completion. It is intended to lead to on-campus pilot projects beginning this academic year that will afford a practical demonstration and evaluation of the utility and effectiveness of the technologies.
- A Request for Information (RFI) about legitimate online music and movie services now available (http://www.educause.edu/issues/rfi/). The Joint Committee does not plan to recommend a particular service, nor can it negotiate any specific online licensing agreement with schools; rather, the goal is to create a knowledge base of information for university administrators and music and movie officials to help facilitate existing or future conversations between legitimate online content services and schools. That RFI was issued in June and the review is underway. The goal of this effort is the implementation of pilot projects at a number of universities to implement campus-based legitimate online music and movie services.
- A recently released white paper, "Background Discussion of Copyright Law and Potential Liability for Students Engaged in P2P File Sharing on University Networks," designed to help school administrators better understand the application of copyright law to peer-to-peer network file

sharing and students' legal liability when they engage in this illegal activity (http://www.acenet.edu/washington/legalupdate/2003/P2P.pdf.)

- This fall, the Committee will release a best practices document intended to serve as a resource to universities and colleges by outlining some of the approaches other schools have taken in setting campus network use policies and in educating students, faculty and staff about respect for copyrights and the liability for illegal file sharing. The Committee believes that the diverse size and varied traditions of numerous universities and colleges precludes a "one-sizes-fits-all" policy. Rather, the document will offer a variety of policies and procedures of demonstrated effectiveness.
- Additionally, the Committee's legislative task force continues its useful dialogue on various legislative issues before Congress.

A complete list of committee members includes:

Cary Sherman
President
Recording Industry Association of America

Irwin Robinson
Chairman
National Music Publishers Association
Chairman and CEO, Famous Music

Graham Spanier
President
Pennsylvania State University

John L. Hennessy
President
Stanford University

Jack Valenti
President and CEO
Motion Picture Association of America

Charles Phelps
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Sherry Lansing
Chairman
Paramount Pictures

Molly Corbett Broad
President
University of North Carolina

Matthew T. Gerson
Senior Vice President, U.S. Public Policy and Government Relations/ Vivendi-Universal

For a cross section of examples (news clips and other information) of what some specific schools and universities are doing to address illegal file sharing, please contact the RIAA.

TESTIMONY BEFORE THE SUBCOMMITTEE ON COURTS, THE INTERNET, AND INTELLECTUAL PROPERTY
COMMITTEE ON THE JUDICIARY
UNITED STATED HOUSE OF REPRESENATIVES
FEBRUARY 26, 2003

GRAHAM B. SPANIER
PRESIDENT OF THE PENNSYLVANIA STATE UNIVERSITY AND
CO-CHAIR OF THE JOINT COMMITTEE OF THE HIGHER EDUCATION AND ENTERTAINMENT COMMUNITIES

Peer-to-Peer File Sharing on University Campuses

Mr. Chairman and Members of the Subcommittee, I appreciate this opportunity to appear before the subcommittee today to discuss the important issue of the use of peer-to-peer file sharing on college and university campuses. As President of The Pennsylvania State University, I am responsible for the management of an institution that has 24 campuses, 5000 faculty, and 83,000 students.

Penn State has actively and comprehensively incorporated information technology into virtually every aspect of its mission of teaching, research, and service. Computer networks have greatly facilitated communication between students and faculty, have enabled new pedagogical and research capabilities, and have enhanced our campus connections with local communities. Information technology has expanded the educational boundaries of traditional classroom teaching and dramatically increased the potential for distance education.

Beyond academic uses, information technology and networked communications have also improved our ability to establish and maintain personal connections with our alumni, with potential students, and with the public. Email, instant messaging, and personal web sites enable our students' ability to reach each other on campus and connect with the world beyond the campus boundaries with ease. Unfortunately, the same technologies that so powerfully expand and enrich the academic and personal experiences of our students and faculty can also be misused. The capacity of information technology to be used for both legitimate and illegitimate purposes is clearly demonstrated by peer-to-peer (P2P) file sharing technologies. P2P technology has the potential to expand dramatically the ease, speed, and breadth of information exchange. Such capacity will clearly benefit a wide range of educational and research activities. Indeed, federal agencies such as the National Science Foundation are funding research into P2P development to realize this potential. But P2P can also be used to carry out the unauthorized retrieval and distribution of copyrighted material.

The misuse of P2P technology on college and university campuses-the subject of this hearing-is a serious problem that is now acutely confronting higher education administrators. Fully understanding the nature and scope of the problem and how to deal with it raises a series of challenges that we are working hard to meet.

University officials are working with representatives of the entertainment industry to address the

problem of misuse of P2P technology. Last October, two letters-one from entertainment industry organizations and one from the six major national higher education associations-were sent to college and university presidents. The higher education letter urged university officials to examine the use of P2P on their campuses and to take appropriate actions to reduce its misuse.

Last summer and fall, university and higher education association officials also began a series of discussions with representatives of the entertainment industry, culminating in the formation of the Joint Committee of the Higher Education and Entertainment Communities, co-chaired by Cary Sherman, President of the Recording Industry Association of America (RIAA), and me; a list of the full committee is attached to my testimony.

The purpose of the committee is two-fold: (1) to examine ways to reduce the misuse of P2P technology on campuses, and (2) to attempt to reduce differences between the higher education and entertainment communities on federal intellectual property legislative issues. The committee met in December to discuss these issues and how to proceed in addressing them. The committee agreed that we would form three task forces: The first focuses on educational efforts about copyrights, rights and responsibilities, and the appropriate and inappropriate use of P2P file sharing. The second deals with the appropriate role, availability, and functionality of technology in managing P2P use. And the third task force will focus on legislative issues.

The work of the task forces is underway. We expect that they will report back to the full committee later this spring, and we will soon thereafter conclude our formal joint activity with a final review of task force work, formulation of recommendations, and a consideration of final steps.

I believe that we have a process that can make real progress in effectively addressing peer to peer piracy on university campuses, and I am hopeful that we can educate our two communities about our common and differing interests and concerns with respect to this and other copyright-related issues. Higher education is clearly on the record in agreeing with the entertainment community that copyright infringement is wrong, and that P2P file trading that constitutes copyright infringement is illegal and should be stopped. We in higher education understand the concerns of the entertainment industry about the impact of P2P misuse on their markets and the loss of opportunities that both creators and consumers may suffer as a consequence. Moreover, university administrators recognize that our institutions have an obligation, through a variety of mechanisms, to educate our students about their legal and ethical responsibilities, not only as members of our university communities, but as members of our society.

We hope, in turn, that entertainment industry officials and policy makers, such as the members of this subcommittee, understand the challenges that lie before university administrators in trying to implement ways to reduce or eliminate inappropriate uses of P2P without at the same time eliminating legitimate uses of P2P technologies; without constricting academic freedom and the free and open exchange of information that underpins the creativity, vigor, and productivity of our education and research programs; and without invading the privacy of our students, faculty, and staff.
A song downloaded or uploaded by a student using P2P typically constitutes copyright infringement; but in selected cases it might also be a fully legitimate, desired fair use of copyrighted material as part of an educational or research project. A technology may exist or be created that can block P2P transactions, but we would be reluctant to embrace technology that would block both legitimate and illegitimate uses indiscriminately. Nor do we wish to stifle the very creativity and experimentation

that has brought us the extraordinary technological capacities that enrich our lives today. Many aspects of this nation's capabilities in information technology and networked communications were developed on research university campuses; we want to be certain that we preserve and nurture that continuing capacity within the academic community for creation and discovery.

Let me illustrate how these concerns play out at my own university. Penn State has a vigorous program of copyright education for our students and employees. Before getting an account, individuals must agree that they understand and will comply with federal and state laws in addition to Penn State's acceptable use policies. The account agreement has a lengthy section dealing with copyright compliance. Likewise, when they get additional services they must agree to policies that include a proscription against copyright infringement.

We also have an indirect enforcement effort. Audio and video files are large, and we monitor the amount, but not the content, of traffic to and from individual machines. Residence Hall users are limited to 1.5 gigabytes of inbound or outbound traffic per week. There are increasingly severe restrictions for offenders who exceed these limitations, beginning with a decrease in the speed allowed for the network connection. For persistent violators there is a complete suspension of network access. The limitation on bandwidth, coupled with the threat of suspension of access, is intended to discourage copyright infringement. Additionally, when notified by copyright holders of infringement, we comply vigorously with the Digital Millennium Copyright Act (DMCA) and immediately suspend access until the issue is resolved. We received 153 such complaints in calendar year 2001. Although we do not currently monitor content to detect the fingerprints of pirated, copyrighted material, we would consider such a possibility if technology, functional for a university of our size, allowed us to maintain the educational principles to which we subscribe.

We also employ proactive technical means to disrupt infringing activities. For example, we routinely scan our networks to find machines that have been compromised in some way or another. One of the primary motivators for intruders to compromise our machines is the establishment of unauthorized outside "Warez" servers, which are generally used for illegally trading copyrighted materials. In just the last few weeks alone, our scanning efforts have located more than 100 such intrusions. Network access to compromised computers is disabled and the illicit software is removed. We also educate the victim whose system has been compromised on how to prevent future compromise of their computer.

Yet despite these educational efforts, despite our compliance with DMCA, and despite our technical interventions, it is probably fair to say that thousands of our students illegally download some amount of copyrighted material. They are typical of college students nationally in this regard and are party to a practice that is morally wrong, is damaging to the entertainment industry, and is inconsistent with the values of honesty and integrity that students more typically profess.

I believe that the work of our joint committee's education and technology task forces will identify a number of useful practices that we intend to share broadly within the higher education community. One of the great strengths of this country's system of higher education is its extraordinary diversity-public and private institutions, research universities, liberal arts colleges, and community colleges. No single set of policies and procedures for managing P2P technologies is likely appropriate for all, but if we identify a number of educational and technological approaches that have been effective in different settings, we can provide useful examples to colleges and universities that will both encourage and guide them in taking actions appropriate to their local circumstances.

At the same time that higher education officials are developing and implementing educational policies and technological interventions, the content community is developing new business models for marketing copyrighted material, including music and movies. I am hopeful that this combination of effort will go a long way to eliminating the misuse of P2P technologies and facilitate the development of the positive potential of P2P.

The capacity for the illegitimate use of P2P is of course not limited to colleges and universities. Indeed, the entertainment industry has sent letters to private sector companies expressing their concern about such misuse. Moreover, as this nation develops greater broadband capacity throughout society, from K-12 education to home connections, we will face the same potential in many other settings.

This is not a new problem; the nation has faced such challenges with each advance of communications technology-the VCR is but one familiar example. The ideal intellectual property model for higher education today, in this new digital territory, is one that finds appropriate and effective ways of balancing, in the tradition of Copyright law, the proprietary rights of copyright owners and the limitations and exceptions to those rights.

Let me close by saying that I believe higher education is taking seriously its responsibility to deal appropriately with these new intellectual property challenges. I believe our cooperation with the entertainment industry in this effort will help both sectors identify appropriate actions to take. I appreciate the interest of this subcommittee in this important issue, and I would be pleased to keep you informed of the work of our joint committee.

Joint Committee of
the Higher Education and Entertainment Communities

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F

The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health

Making it Work

Paul VANDOREN and Jean Charles Van EECKHAUTE*

I. INTRODUCTION

On 30 August 2003, after several months of deadlock, the World Trade Organization (WTO) General Council adopted the long-delayed Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the Decision).[1]

The breakthrough deal (often referred to as the "Perez Motta text", after the former Chairman of the Council for TRIPS) now allows WTO Members to issue compulsory licences with a view to exporting patented medicines to countries with no manufacturing capacity in the pharmaceutical sector. Doing this, this Decision fulfils the mandate given by the Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration).[2]

This Declaration broke new ground in clarifying the relationship between the TRIPS Agreement and public health policies, while reaffirming the Member's commitment to the Agreement. It puts the emphasis on the right balance to be struck between intellectual property and broader policy objectives, in particular public health. This balance is a fundamental principle of intellectual property, and is laid down in Articles 7 and 8 of the TRIPS Agreement ("objectives" and "principles") which refer, *inter alia*, to the need to take measures to protect public health and nutrition, the prevention of the abuse of intellectual property rights, the pursuit of social and economic welfare and the need to strike a proper balance of rights and obligations.

* Respectively, Head of Unit "New Technologies, Intellectual Property, Public Procurement" and Administrator at the European Commission, DG Trade, Brussels, Belgium.

Both authors represented the EU in the WTO negotiations on TRIPS and Public Health. The views expressed in this article are those of the authors and cannot be attributed to the European Commission. They may be contacted at: «paul.vandoren@cec.eu.int», or «jean-charles.van-eeckhaute@cec.eu.int».

[1] WTO reference, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health—Decision of 30 August 2003*, WT/L/540 of 2 September 2003.

[2] WT/MIN(01)DEC/2 of 14 November 2001.

The Doha Declaration confirmed the WTO Members' right to issue compulsory licences for public health purposes. But this raised a practical problem for countries which do not dispose of a pharmaceutical industry, making it impossible to use this instrument in practice. Therefore, recognizing that the use of compulsory licences remained problematic for countries with insufficient or no manufacturing capacities in the pharmaceutical sector, the TRIPS Council was instructed to find an expeditious solution to this problem by end 2002 (Paragraph 6 of the Declaration).[3]

The negotiations on Paragraph 6 of the Doha Declaration took longer than the negotiation of the Declaration itself. This was due to the different legal nature of the challenges. The main objective of the Doha Declaration was to clarify and interpret what was already written in the TRIPS Agreement. The Declaration represented a significant breakthrough and has interpretative value for the TRIPS Agreement,[4] but it has not altered the Agreement. The solution to Paragraph 6, however, necessitated a far more "drastic" legal solution that would allow Members to do something that was not allowed under the TRIPS Agreement. For this reason, and also because of the political sensibility and the diverging interests involved, it took almost two years of protracted negotiations and near-compromises to come to this result, which represents a remarkable achievement.

The WTO's Council for TRIPS played a major role in the drafting of the Decision. Throughout 2002, the main protagonists submitted various oral and written Communications,[5] and intensive exchanges of view took place. The process intensified in November and December 2002, when consultations and negotiations were held in more informal settings. In late December 2002, Ambassador Perez Motta, then Chair of the TRIPS Council, submitted a number of drafts. The last draft presented was the text of 16 December 2002. Although a number of developing countries had difficulties with the conditions on trade diversion, it was endorsed by almost all of the WTO Membership, with the notable exception of the United States, which considered that the disease scope of the Decision was too broadly defined. This led to a deadlock in the negotiations. In January and February of 2003, several compromise proposals[6] were put on the table to bring the United States on board, but none of them managed to attract

[3] Paragraph 6 of the Doha Declaration: "We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

[4] The Declaration is to be considered as a "subsequent practice" in the application of the TRIPS Agreement, within the meaning of Article 31(1)(b) of the Vienna Convention on the Law of Treaties, which establishes the agreement of the parties regarding its interpretation.

[5] See, *inter alia*, Communications by the African Group (IP/C/W/351 and IP/C/W/389); Brazil on behalf of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela (IP/C/W/355); the EC (IP/C/W/339 and IP/C/W/352); the United Arab Emirates (IP/C/W/354); and the United States (IP/C/W/340 and IP/C/W/358).

[6] Notably by the EU (7 January 2003, see, JOB(03)/9 of 24 January 2003); Japan (JOB(03)/19 of 6 February 2003); and the Chairman of the TRIPS Council (February 2003). The EU proposal purported to maintain a broad disease scope, while introducing a mechanism that would foster U.S. confidence in the system. The main idea was that for public health diseases other than those which had been listed by the United States as acceptable in December 2003, Members could seek (non-binding) advice from the World Health Organization in case of doubt.

consensus. The following months were marked by informal contacts between the United States and developing countries and even direct contacts between the pharmaceutical industry and certain developing countries. This close involvement of industry in a negotiation process, going beyond standard lobbying efforts, was rather unusual in the context of an international organization like the WTO. These meetings proved useful in clarifying positions, as in the last few months before the Cancun Ministerial, the United States gradually relaxed its position and finally declared its readiness to adhere to the Perez Motta text, provided it was accompanied by a statement where WTO Members would confirm their intention not to abuse the system for commercial purposes. Further to this positive signal, the current Chairman of the TRIPS Council held talks with the U.S. Government and a number of key developing countries (Brazil, India, South Africa and Kenya) in order to bridge the confidence gap.

These consultations resulted in a Statement, which was read out by the Chairman of the WTO General Council just before the adoption of the Decision.[7] It confirms the common understanding of all WTO Members that the primary objective of the Perez Motta text is to protect public health and that it should be used in good faith. It stresses the need to ensure that medicines reach populations in need and that they should not be diverted from the markets for which they are intended. The statement is wholly complementary to the Perez Motta text. It does not affect it in any respect and cannot be read as creating new conditions. The Perez Motta text remains the only valid legal text, setting out the conditions for the use of compulsory licences for export.

In the key paragraph of this statement. Members recognize that the system established "should be used in good faith to protect public health and ... not be an instrument to pursue industrial or commercial objectives." This confirms the basic objective of the Perez Motta text, which establishes a demand-driven process to deal with difficulties experienced by countries with no or insufficient manufacturing capacities. Its primary objective is to address public health problems. Contrary to what has been stated in some quarters, this does not preclude the system from having commercial and/or industrial consequences on companies and/or countries or from being complementary to (existing) commercial and/or industrial objectives.

Although it was welcomed by all WTO Members and by the World Health Organization as a major achievement, the Perez Motta text has not been free of criticism. Certain circles have qualified the text as a rift in intellectual property protection, and raised the spectre of massive abuses by generic producers in certain emerging countries, leading to a flood of generic copies of "lifestyle" blockbusters such as baldness cures. Others have depicted the Decision as far too complex to be effectively used by developing countries. Both sides are wrong, and should be aware of their responsibilities; raising doom scenarios often carries the risk of self-fulfilling prophecy.

[7] JOB(03)/177 of 27 August 2003. Text available at: «http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm».

The purpose of this contribution is to provide some insights into the Decision, and to show that it sets up a balanced and flexible mechanism, which provides for a workable framework to allow for exports of medicines produced under a compulsory licence, while adequately addressing concerns on trade diversion.[8]

II. Legal Basis and Structure of the Decision

The deal on Paragraph 6 takes the form of a Decision of the General Council.[9] It consists of three waivers[10] (two related to Article 31(f) TRIPS[11] and one related to Article 31(h) TRIPS[12]) as well as a number of understandings and *sui generis* decisions. The legal basis and the legal status of each of the paragraphs of this Decision, as well as the related Statement, raise a number of interesting legal questions (especially as regards enforcement and dispute settlement), but do not fall within the object of the present article.

The pivotal part of the Decision is the waiver of Article 31(f), allowing Members to grant compulsory licences with a view to exporting pharmaceutical products to countries with no or insufficient manufacturing capacities.

The TRIPS Agreement does not categorically prohibit exports of products manufactured under a compulsory licence. Article 31(f) TRIPS specifies that a compulsory licence must be "predominantly for the supply of the domestic market" of the Member granting the licence, thus allowing for the export of a non-predominant part. Furthermore, this condition does not apply where a licence is issued in order to remedy an anti-competitive practice.[13] In addition, it should not be forgotten that medicines which are not patented can be freely exported.[14] However, there was no workable legal basis to grant for a compulsory licence with the exclusive aim of

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[8] For more detailed information on the issues at stake and the negotiation process, see, *inter alia*, F.M. Abbott, *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health*, Occasional Paper No. 9, Quaker UN Office, February 2002; J.H.J. Bourgeois and T.J. Burns, *Implementing Paragraph 6 of the Doha Declaration on TRIPS and Public Health—The Waiver Solution*, 5 J.W.I.P. 6, November 2002; C. Corea, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, World Health Organization, 2002; F. Ismail, *The Doha Declaration on the TRIPS Agreement and Public Health and the Negotiations in the WTO on Paragraph 6—Why PhRMA needs to join the Consensus*, 6 J.W.I.P. 3, May 2003, p. 393; J.C. Van Eeckhaute, *The Debate on the TRIPS Agreement and Access to Medicines in the WTO: Doha and Beyond*, Pharmaceuticals Policy and Law, Volume 5, 2002.

[9] Article IV:2 of the Marrakech Agreement Establishing the WTO (WTO Agreement) empowers the General Council to replace the Ministerial Conference when the latter is not in session. Article IV:1 of the WTO Agreement grants the Ministerial Conference of the WTO the authority to take Decisions on all matters under any of the Multilateral Trade Agreements.

[10] Article IX:3 of the WTO Agreement empowers the Ministerial Conference to waive an obligation imposed on a Member by any WTO Agreement.

[11] Paras. 2 and 6.

[12] Para. 3.

[13] Article 31(k) TRIPS. Logically, the anti-competitive practice to be addressed here must occur on the territory of the Member granting the licence.

[14] This mainly concerns: (a) developing countries which have only recently introduced patent protection and which can still make generic versions of medicines that were already on their market before the introduction of product patents on pharmaceuticals; (b) developing countries which rely on the 2005 deadline of Article 65:4 TRIPS for granting product patents to medicines; (c) least-developed countries which rely on the 2016 deadline of Paragraph 7 of the Doha Declaration for granting pharmaceutical patents; and (d) any country where, for whatever reason, no patent has been filed for a given product.

exporting the production; hence, the need for an amendment of Article 31(f), or at least a waiver.

Throughout the negotiations, a large number of developing countries strongly advocated an approach based on Article 30 of the TRIPS Agreement. Article 30 allows Members, under certain conditions, to provide for limited exceptions to the rights conferred by a patent. The basic difference with an Article 31-approach is that an Article 30-approach would result in a general exception under a Member's patent law, allowing any producer to use the patent without further authorization (when all conditions are fulfilled), while an Article 31-based approach necessitates the granting of a compulsory licence on a case-by-case basis. Initially, the EU also expressed willingness to consider the Article 30 avenue,[15] but in view of the vigorous opposition of the United States and other industrialized countries, it became rapidly clear that this option was not viable.[16] The EU therefore concentrated on the other option, i.e. an amendment of Article 31(f). But most industrialized Members, fearing the consequences of an amendment of the TRIPS Agreement, preferred to address the issue through a waiver or even a moratorium on dispute settlement, which would leave the TRIPS Agreement untouched.

However, the waiver introduced by the Decision is only a transitory and provisional measure; the Decision expressly stipulates it will be replaced by an amendment. Work to this effect shall have to be initiated by the TRIPS Council by the end of 2003 with a view to its adoption within six months. This is important; it would have been rather paradoxical to solve a structural problem through an instrument (i.e. a waiver) designed to temporarily address exceptional circumstances.

The Article 31-based approach has raised comments that the system would be unnecessarily cumbersome, because two compulsory licences would have to be issued: one in the importing country and one in the exporting country. Surprisingly, this comment mainly comes from those who have claimed that compulsory licensing was amongst the most adequate instruments to ensure the availability of affordable drugs.

However, procedures to grant compulsory licences are not necessarily cumbersome and lengthy. The procedural requirements of Article 31 TRIPS are minimal and flexible, and also provide for a fast-track procedure as regards situations of extreme urgency or national emergency (which covers, in any event, AIDS, tuberculosis and malaria, but also potentially a range of other situations or diseases). What matters is that the procedure be transparent and the rights of defence of the right holder be guaranteed. This include the availability of effective judicial or administrative review procedures,[17]

[15] Concept Paper Relating to Paragraph 6 of the Doha Declaration. Communication from the EC to the TRIPS Council, 4 March 2002, IP/C/W/339.

[16] Even before the Doha Ministerial, informal suggestions to explore an Article 30-approach, including by the EC, had already met fierce opposition, which was one of the reasons why the "Paragraph 6" issue could not be solved in Doha.

[17] Article 31(i) of the TRIPS Agreement.

but it must be noted that nothing in the TRIPS Agreement obliges Members to suspend a compulsory licence pending litigation. So, for WTO Members it is a question of tailoring the granting procedure in the most effective way. Where two compulsory licences would have to be issued, it would mainly be a question of adequately matching and co-ordinating procedures in the producing and importing country (or countries).

It must also be borne in mind that, in many developing or least-developed countries, not all medicines are patented (or even patentable)[18] for the time being, in which case no licence would be required in the country of destination.

Finally, the Decision specifies that, where two compulsory licences must be issued, there shall be no double remuneration.[19] The obligation of Article 31(h) TRIPS that equitable remuneration must be paid to the right holder is waived for the importing country. As a result, remuneration will have to be paid in the exporting country only, taking into account the economic value of the compulsory licence in the importing Member. This makes sense from an economic point of view. First, one can expect that the ability to pay remuneration will be higher in the country of manufacture than in the importing country. Second, as the product will be sold or otherwise distributed in the importing country, it is the "market value" of the licence in that country which should determine the level of remuneration.

III. SCOPE OF THE DECISION

A. PRODUCT SCOPE

The scope of the Decision is not limited to medicines but to "pharmaceutical products", defined as "any patented product, or product manufactured through a patented process, of the pharmaceutical sector."[20] The Decision further clarifies that active ingredients necessary for the manufacture of pharmaceutical products and diagnostic kits needed for their use would be included.[21] Vaccines are not expressly included, although most Members, including the EC, advocated their express inclusion. We would argue that the term "product ... of the pharmaceutical sector" should be read as including vaccines, as they are usually produced by companies belonging to the pharmaceutical sector.

B. DISEASE SCOPE

This had already been a major issue of discussion in the run-up to the Doha

[18] Footnote 6 to the Decision specifies that it is without prejudice to the right of least-developed country Members to delay introduction of patents (on medicines) until 2006 or beyond (i.e. at least 2016 as agreed in Paragraph 7 of the Doha Declaration and implemented through a Decision of the TRIPS Council of 27 June 2002: IP/C/25).

[19] Para. 3.

[20] Para. 1(a).

[21] Id.

Declaration. The compromise formula reached in Doha was reflected in its Paragraph 1 which referred to "public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics", a formula containing sufficient "constructive ambiguity" to accommodate proponents of a broad disease scope. Despite attempts to re-open this discussion, the disease scope of the Decision is defined by reference to Paragraph 1 of the Doha Declaration.[22] It is precisely this formulation that caused concern to the pharmaceutical industry and led the United States to block the deal, but the United States finally accepted this formula. It is now generally recognized that the disease scope of the Doha Declaration, and hence of the Decision, is flexible, and should encompass any serious public health problem.

C. COUNTRY SCOPE

1. *Countries Eligible for Import*

Basically, eligibility to import under the Decision is determined by an objective criterion: a Member has to establish that it has "insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question."[23] Least-developed country Members are automatically deemed to be in such a situation.[24]

An Annex to the Decision clarifies that insufficient or no manufacturing capacities can be established in two ways, but does not add much to what is already in the Decision. The first option is that "the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector". The alternative option is that a Member, if it has some manufacturing capacity in this sector, can examine this capacity and find that (excluding the patent owner's capacity) it is currently insufficient for the purposes of meeting its needs. The Annex adds that when it is established that such capacity has become sufficient to meet the Member's needs, it can no longer rely on the system.

The Decision does not prescribe any scientifically watertight method to establish lack of manufacturing capacity; the self-assessment of the available capacity and the subsequent conclusion fall under the exclusive responsibility of the Member itself, within the limits indicated in the Decision (and in the Annex). What matters is that the Member in question be able to explain how the self-assessment has been performed. The related notification requirement is for information purposes only. It cannot be reversed or rejected by any other Member or by the TRIPS Council.

The use of the term "for the product(s) in question", both in the Decision and the Annex, indicates that manufacturing capacity must be assessed on a product-by-product

[22] Id.
[23] Para. 2(a)(ii); see "eligible importing Member" under Para. 1(b).
[24] See Para. 1(b).

basis, rather than on a sectoral basis. In other words, disposing of production capacity for aspirins, does not necessarily imply capacity to produce, for example, anti-retrovirals.

Logically, countries which do dispose of sufficient capacity cannot use this system as importers. In this spirit, developed countries have announced that they will not import under the system,[25] while high-income developing country Members[26] have made a statement that they would not use the system except "in situations of national emergency or other circumstances of extreme urgency". The ten countries which will join the EU in May 2004[27] have made a similar statement. Once they will have joined the EU, they will not use the system as importers at all.

2. *Exporters*

All WTO Members qualify as exporters.[28] At a certain stage in the negotiations, some industrialized country Members advocated a system whereby developed country Members would be squarely excluded as exporters, or where they could only do so where it was established that no developing country Member was able to meet the demand for a certain product. Since the objective of the system is to make sure that countries in need can appeal on the best available sources of supply (both in terms of price and quality), there was no valid argument against the developed countries' participation as producers/exporters. Consequently, such a limitation was rejected.

IV. CONDITIONS ATTACHED TO THE USE OF THE SYSTEM

Under the Decision, the use of the system is subject to a number of conditions aimed at preventing trade diversion and at ensuring transparency. They require measures to be taken either directly by the Members concerned, or to be imposed on the licensee, through the terms and conditions of the compulsory licence. They are not only aimed at addressing the concerns of the pharmaceutical industry with regard to the risk of unjustified parallel markets, but also at marking sure that the products manufactured under this mechanism effectively reach those in need.

These conditions were carefully crafted. The most important of them are qualified by a standard of reasonableness and a proportionality requirement, so as to make sure that they do not place an unreasonable burden on Members or do not render the system unworkable. Notwithstanding these principles, respect of these commitments, and sincere efforts by all Members to live up to them, within reason and within the limits

[25] They are mentioned in a footnote to Paragraph 1(b) of the Decision: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

[26] Chinese Taipei, Hong Kong, Israel, Korea, Kuwait, Macao, Mexico, Qatar, Singapore, Turkey and the United Arab Emirates.

[27] Slovenia, Estonia, Lithuania, Latvia, Hungary, Slovakia, Czech Republic, Poland, Malta and Cyprus.

[28] Para. 1(c).

of their capacities, are key. They will be essential in maintaining confidence within the system. The efficiency of these measures will result from the interplay of the measures taken by exporting, importing and third-country Members and the notification requirements.

Compulsory licences issued under the Decision remain subject to the relevant requirements of Article 31 of the TRIPS Agreement. The Decision expressly confirms that these conditions do not encroach on the existing modalities and flexibilities of Paragraph 31 of the TRIPS Agreement.[29]

A. MEASURES AGAINST TRADE DIVERSION

The importing Members must take "reasonable measures, within their means, proportionate to their administrative capacities and to the risk of trade diversion" to prevent re-exportation of the products that have been imported into their territories under the system.[30]

The wording used here is extremely careful in order to ensure that importing countries (many of them will be least-developed countries) should not bear an unreasonable burden. It would, indeed, be unreasonable to expect least-developed countries to put a customs guard behind every shipment. The purpose of this "best endeavours" commitment is to ensure that all countries involved take their part of the responsibility, within reason, to prevent trade diversion. It is within the discretion of each Member to determine exactly which measure(s) should be taken, taking into account their capacities and the risk of trade diversion. Examples of measures that could be taken range from specific border measures to requesting distributors to undertake in writing that they will not divert the products away from the intended destinatories. Developed country Members have committed to provide technical assistance in this respect.

The exporting Member must guarantee, through the terms of the compulsory licence, that the following conditions are met:

- the compulsory licensee should manufacture no more than the amount necessary to meet the needs of the importing country (or countries). However, this does not preclude the compulsory licensee to produce additional amounts under a compulsory licence for internal use or under other compulsory licences for export to other countries (and, likewise, nothing precludes the issuing of one licence for production and export to several

[29] Para. 9: "This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement."

[30] Para. 4.

countries, in case concurring demands have been made for the same product);[31]

- the entirety of this production must be exported to the Member(s) which has/have notified its/their needs. This condition is a key safeguard against trade diversion as it makes sure that no export takes place to countries which have not notified their needs;[32]

- products must be clearly identified as being produced under the system through specific labelling or marking and special colouring/shaping of the products themselves, "provided that such distinction is feasible and does not have a significant impact on price".[33] Here again, there is an important proportionality requirement in order to make sure that this condition would not render production unfeasible or cost-ineffective, especially as regards colouring/shaping. In particular, it would become counter-productive if the use of a different colour or shape for the pills would necessitate new bio-equivalence studies and new marketing approval (and thus lengthy procedures).

As far as the labelling and marking requirement is concerned, there should be no specific problem; in certain countries, most notably in India, generic copies of virtually all types of medicines are routinely produced. Naturally, these generic producers use brands, labels, names and packages that are different to those of the brand holders. It is therefore generally considered that this requirement does not affect the production costs.

In addition, all Members (this applies in particular to rich country markets or transit countries) must ensure the availability of effective legal means to prevent the importation or diversion into, and sale in, their territories of products produced under the system, using the means already required to be available in the TRIPS Agreement (i.e. Part III of the TRIPS Agreement on the implementation of intellectual property rights).[34]

B. NOTIFICATION REQUIREMENTS

The importing Member must submit a notification to the TRIPS Council that:

- specifies the names and expected quantities of the product(s) needed;

[31] Para. 2(b)(i).
[32] Id.
[33] Para. 2(b)(ii).
[34] Para. 5. On 26 May 2003 the European Union adopted Council Regulation (EC) No. 953/2003 to avoid trade diversion into the European Union of certain key medicines. This Regulation aims at preventing the re-entry into the EU of medicines that have been sold at strongly reduced prices ("tiered prices") to certain developing and least-developed countries by their original manufacturers (research-based or generic). It does not apply to products manufactured and distributed pursuant to the Decision.

- confirms that it has insufficient or no manufacturing capacities in the pharmaceutical sector; and
- confirms that, when the product is patented in its territory, it has granted or intends to grant a compulsory licence.[35]

The exporting Member must:

- notify to the TRIPS Council the granting of the licence, including the conditions attached to it. The information to be provided includes the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. This notification must also indicate the address of the Website where the licensee has posted the essential information concerning its licence;[36]
- ensure (as part of the conditions of the compulsory licence) that, before shipment begins, the licensee notifies detailed information on the quantities being supplied to each destination and the distinguishing features of the product.[37]

These notifications are for the sake of transparency and information only—full transparency being the best guarantee against diversion and for an effective functioning of the system. As is made clear in the Decision, the notifications do not amount to authorization requests; Members concerned will not need to be approved by any WTO body in order to be able to use the system.[38] They can automatically use the system once they have made the notifications.

The TRIPS Council is called to play an important role as a forum to discuss issues related to implementation of the Decision, as part of the Council's general competence to monitor the operation of the TRIPS Agreement. However, the Decision does not create new powers for the TRIPS Council.[39] Like any matter related to the TRIPS Agreement, issues related to the implementation of the Decision can be raised before the TRIPS Council and discussed by the latter.[40] The powers and prerogatives of the Council remain those determined by the TRIPS Agreement and the Rules of Procedure of the Council. It should also be borne in mind that, when decisions are taken by the TRIPS Council, they are taken by consensus; they cannot be

[35] Para. 2(a).
[36] Para. 2(c).
[37] Para. 2(b)(iii).
[38] See footnotes 2 and 8 of the Decision.
[39] There is one exception though—Paragraph 8 of the Decision transfers the General Council's competence under Article IX:4 of the WTO Agreement to review waivers to the TRIPS Council (although such transfer of competences is not expressly foreseen under the WTO Agreement).
[40] Article 68 of the TRIPS Agreement provides that: "The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights ...".

taken against the will of any Member. Finally, the TRIPS Council is not entitled to take binding decisions on disputes amongst Members (this is a prerogative of the Dispute Settlement Body).

V. REGIONAL DIMENSION

Paragraph 6 of the Decision introduces a specific waiver that allows countries that are Members of certain regional groupings to further export products, which have been produced or imported under a compulsory licence, to other Members of that regional grouping. The importance of this waiver lies in the possibility to further export products that have been imported under a compulsory licence, thus promoting economies of scale and bulk purchasing.

This waiver applies to developing or least-developed countries that are party to a "regional trade agreement"[41] of which at least half of the Members are least-developed countries. This condition means that, *de facto*, it will mainly benefit African regional groupings. The regional approach was a specific request from African Members, although, at some stages in the negotiations, other Members also expressed some interest.

This waiver is certainly helpful, but not entirely satisfactory though; countries where the product is patented will still have to issue a compulsory licence for import. The principle of territoriality of patents made it impossible to set up a system whereby a compulsory licence issued by one Member of a regional grouping would automatically have full effect on the territory of the other Members. According to this principle, a patent is valid only in the territory of the country which has granted the patent, and can have legal effects only in that country. It remains independent from any patent for a similar product granted by another country.[42] As a result of this principle, a compulsory licence can apply only to the patent that exists in the territory of the country granting the licence, and cannot have any effects on a patent granted by another country.

The best approach to these problems lies in regional approaches to patenting and compulsory licensing, i.e. the creation of regional patent offices, which would grant regional patents, it being assumed that they would entirely replace national patents. In those cases where patents are granted by regional groupings, and where a single patent applies to all the countries of that regional grouping, the granting of one single compulsory licence, that would apply in all those countries, would be a logical consequence. In this case, the territoriality principle would remain preserved, as the

[41] Defined as a regional trade agreement within the meaning of Article XXIV of GATT 1994 or the so-called "Enabling Clause" (Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries: L/4903).

[42] Article 4*bis* of the Paris Convention for the Protection of Industrial Property, as incorporated by reference into the TRIPS Agreement.

territory of the single patent would correspond to the territory of the regional grouping. This type of regional approach would be extremely helpful for developing countries in sharing the burden of implementing the TRIPS Agreement and the Doha Declaration through a pooling of resources.

The *Organisation Africaine de la Propriété Intellectuelle*, which groups sixteen, mainly French-speaking, countries of West-Africa is an interesting model to follow. Its constitutive text, the Revised Bangui Agreement, establishes common intellectual property rules and procedures, which provide, *inter alia*, for the granting of regional patents.[43] However, it does not provide for a common compulsory licensing procedure (although this is perfectly compatible with the TRIPS Agreement) and provides that compulsory licences cannot extend to the act of importing. This shows that there is a pressing case for appropriate technical assistance, allowing developing countries to make full use of the flexibilities of the TRIPS Agreement. In this regard, Paragraph 6 of the Decision recognizes the importance of developing regional patent systems and contains an undertaking by developed country Members to provide specific technical co-operation to this effect.

VI. TRANSFER OF TECHNOLOGY

Another essential issue for African countries was transfer of technology. Paragraph 7 of the Decision recognizes the desirability of promoting the transfer of technology and capacity-building in the pharmaceutical sector, in order to overcome the problem identified in Paragraph 6 of the Declaration. To this end, the Decision encourages eligible importing Members and exporting Members to use the system set out in this Decision in a way which would promote this objective. Members undertake to co-operate in paying special attention to the transfer of technology and capacity-building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66:2 of the TRIPS Agreement (in which developed country Members undertake to provide incentives to their companies to transfer technology to least-developed countries) and Paragraph 7 of the Declaration (re-affirming the developed country Members' commitment under Article 66:2).

VII. CONCLUSIONS AND FUTURE WORK

The Decision has boosted the expectations of many developing and least-developed country Members of the WTO. It provides them with the much needed legal security and a roadmap of how to go ahead without running the risk of being legally or otherwise challenged. This security is essential for these countries. In this respect, it will be important to avoid interpreting the Perez Motta text in an overly restrictive way,

[43] For further information, see E.S. Nwauche, *An Evaluation of the African Regional Intellectual Property Right Systems*, 6 J.W.I.P. 1, January 2003.

which could, in practice, hamper its efficiency.[44] Likewise, abuse of the system for reasons other than those stated in the Decision, would severely affect the confidence among Members, which would have a devastating effect on the workability of the system.

The proof of the pudding will be in the eating. The onus is therefore on all WTO Members to create the necessary conditions to ensure that the system established by the Decision can work. Important efforts will have to be made by those countries which are prepared to export under the system; they will have to create a new legal basis in their patent law to grant compulsory licences for export. For many Members, especially developing country Members, which have only just made significant efforts to bring their legislation into line with the TRIPS Agreement, this will be quite a challenge. It may also require the introduction or updating of administrative and/or judicial structures, procedures and disciplines. In many instances, sound technical assistance and capacity-building will be paramount to enable these countries to recognize and act on the implications of the TRIPS Agreement on public health policies and establish workable laws, procedures and practices to give effect to the Doha Declaration and to the Decision. In a Communication of June 2003 to the TRIPS Council,[45] the EC committed itself to providing technical assistance to that effect, if requested, and called upon multilateral technical assistance providers to do so as well. The Decision reinforces the case of appropriate technical assistance.

At WTO level, the Decision will have to be transposed into an amendment which should faithfully reflect the relevant parts of the Perez Motta text. The timetable established by the Decision (i.e. initiation of work in December 2003 and conclusion after six months) must be scrupulously respected.

However, this Decision only adds one little, albeit important, piece to the jigsaw of measures to tackle the public health situation in the developing world. Recent economic studies have shown that, especially as concerns HIV/AIDS, the provision of anti-retrovirals is a sound policy option that can be implemented in economically efficient and cost-effective ways, even in poorer countries.[46] So, now that the Decision provides for a safe legal environment we have to get the economics and the infrastructure right. Just like all economic operators, generic manufacturers will need solvable demand. Even at lower prices, medicines may remain unaffordable for the poorest populations if no adequate funding and purchasing mechanisms are put in place.

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[44] In this respect, it should be noted that, pursuant to its Paragraph 10, non-violation complaints cannot be brought against measures taken in conformity with the waivers set out in the Decision. This is very important, because non-violation complaints carry the risk of being used to circumscribe the flexibilities under the TRIPS Agreement. There is currently a temporary moratorium on non-violation complaints under the TRIPS Agreement, as a Decision on their applicability still has to be taken by the TRIPS Council (see Article 64 of the TRIPS Agreement). A vast majority of WTO Members take the view that they should not apply.

[45] Communication by the European Communities on the Implementation of the Doha Declaration on the TRIPS Agreement and Public Health, IP/C/W/402 of 24 June 2003.

[46] See, J.P. Moatti, T. Barnett, B. Cariat, Y. Soteyrand, J. Dumoulin and Y.A. Flori (eds.), *Economics of AIDS and Access to Healthcare in Developing Countries: Issues and Challenges*, ANRS, France, 2003.

Despite important and visible efforts that have been made lately, the existing commitments remain largely insufficient. The developed world bears a heavy responsibility in this regard. It is funding which will, at the end of the day, make the difference. In addition, investments will also have to be made in the basic health facilities and infrastructure to channel the medicines to the patients.

The extent to which the Decision will really be used is difficult to predict. It will, as mentioned above, depend on the purchasing capacities of the *demandeurs*, but several other factors will have to be taken into account. For example, India, which is the world's main producer, will, for some time, still be able to export medicines without the need of granting compulsory licences (pursuant to Article 65:4 of the TRIPS Agreement, India will have to grant product patents for medicines only as from 2005). Another important element to take into account is that, as shown by Brazil, the usefulness of compulsory licences comes mainly in the leverage they give to developing countries in price negotiations with pharmaceutical companies. In other words, compulsory licences can deliver the expected results, i.e. making medicines more affordable, without being actually granted.

On the intellectual property side, the WTO now offers a solution that provides an expeditious and effective relief to the problems experienced by developing countries in the context of public health. The full implementation of the Doha Declaration will be a crucial test for the TRIPS Agreement. It is paramount to leave room for a flexible implementation of the TRIPS Agreement and the Declaration, so as to allow developing countries to smoothly adapt their intellectual property systems in a way that allows them to address their specific concerns and serve public interest. If this flexible legal environment is not guaranteed and preserved, implementation of the TRIPS Agreement, especially as regards pharmaceutical patents, will remain a permanent source of problems and friction.

G

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108TH CONGRESS
1ST SESSION

H. R. 2391

To amend title 35, United States Code, to promote research among universities, the public sector, and private enterprise.

IN THE HOUSE OF REPRESENTATIVES

JUNE 9, 2003

Mr. SMITH of Texas (for himself, Mr. BERMAN, Mr. CONYERS, Mr. COBLE, Mr. GOODLATTE, Mr. GREEN of Wisconsin, Ms. HART, Mr. BOUCHER, Ms. LOFGREN, Mr. WEXLER, and Ms. BALDWIN) introduced the following bill; which was referred to the Committee on the Judiciary

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A BILL

To amend title 35, United States Code, to promote research among universities, the public sector, and private enterprise.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Cooperative Research and Technology Enhancement (CREATE) Act of 2003".

SEC. 2. LIMITATION ON NONPUBLIC INFORMATION IN OBVIOUSNESS DETERMINATIONS.

(a) CONDITIONS FOR PATENTABILITY; NOVELTY.—Section 102(f) of title 35, United States Code, is amended

by inserting after "patented," the following: "except that subject matter under this subsection shall not be considered prior art or as evidence of obviousness under section 103 of this title,".

(b) CONDITIONS FOR PATENTABILITY; NONOBVIOUSNESS.—Section 103(c) of title 35, United States Code, is amended to read as follows:

"(c) Subject matter developed by another person, which qualifies as prior art only under one or both of subsections (e) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time of the earliest filing date for which a benefit is sought under this title, owned by the same person or subject to an obligation of assignment to the same person.".

SEC. 3. EFFECTIVE DATE.

(a) IN GENERAL.—The amendments made by this Act shall apply to any patent granted before, on, or after the date of the enactment of this Act.

(b) SPECIAL RULE.—The amendments made by this Act shall not affect any final decision of a court or the United States Patent and Trademark Office rendered before the date of the enactment of this Act, and shall not affect the right of any party in any action pending before the United States Patent and Trademark Office or a court

on the date of the enactment of this Act to have that party's rights determined on the basis of the provisions of title 35, United States Code, in effect on the day before the date of the enactment of this Act.

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Reported out of H.L.C. Subcommittee

AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 2391 OFFERED BY MR. SMITH OF TEXAS AND MR. BERMAN

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Cooperative Research and Technology Enhancement (CREATE) Act of 2003".

SEC. 2. COLLABORATIVE EFFORTS ON CLAIMED INVENTIONS.

Section 103(c) of title 35, United States Code, is amended to read as follows:

"(c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time of the earliest filing date for which a benefit is sought under this title, owned by the same person or subject to an obligation of assignment to the same person. For purposes of this subsection, subject matter and a claimed invention owned by parties to a joint research agreement shall be considered to be owned by the same person or subject to an obligation of assignment to the same person

if the claimed invention arises from the terms of the joint research agreement and the agreement was entered into before the earliest filing date for which a benefit is sought under this title.

"(2) In this subsection, the term 'joint research agreement' means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.".

SEC. 3. EFFECTIVE DATE.

(a) IN GENERAL.—The amendments made by this Act shall apply to any patent granted before, on, or after the date of the enactment of this Act.

(b) SPECIAL RULE.—The amendments made by this Act shall not affect any final decision of a court or the United States Patent and Trademark Office rendered before the date of the enactment of this Act, and shall not affect the right of any party in any action pending before the United States Patent and Trademark Office or a court on the date of the enactment of this Act to have that party's rights determined on the basis of the provisions of title 35, United States Code, in effect on the day before the date of the enactment of this Act.

Amend the title so as to read: "A bill to amend title 35, United States Code, to promote cooperative research

involving universities, the public sector, and private enterprises.".

THE COOPERATIVE RESEARCH AND TECHNOLOGY ENHANCEMENT (CREATE) ACT OF 2003

H.R. 2391

PURPOSE AND SUMMARY

The purpose of the CREATE Act is to promote collaborative research between private, public and non-profit entities to the betterment of the American public, the stimulation of the U.S. economy, and the promotion of the progress of science. This objective is accomplished through a clarification to a 1984 amendment to the Patent Act (subsection 103(c) of title 35, United States Code).

The clarification is necessary because of a 1997 decision of the U.S. Court of Appeals for the Federal Circuit. In *Oddzon Products, Inc. v. Just Toys, Inc.*[1], the appellate court interpreted subsection 103(c) to allow free communication among research scientists in one organization regarding development of an invention, as not applying to the same free communication if made among collaborators from different organizations. The *Oddzon* decision is having a chilling effect on research collaborations among government, university and corporate inventors. To remedy this problem, legislation is necessary to amend subsection 103(c) to ensure that information shared among researchers engaged in scientific collaboration cannot be used to preclude patentability or invalidate a patent under subsection 103(c) where that shared information qualifies as prior art under subsections 102(e), (f) or (g). If adopted, the proposed amendment to subsection 103(c) will clarify the law and will prevent the chilling effect that the *Oddzon* decision is having on public, private and non-profit research collaborations.

LEGISLATIVE BACKGROUND

During the 107th Congress, the Subcommittee on Courts, the Internet, and Intellectual Property of the House Committee on the Judiciary held an oversight hearing on problems associated with "Patent Law and Non-Profit Research Collaboration." Testimony was received from Dr. Carl Gulbrandsen, Managing Director of the Wisconsin Alumni Research Foundation ("WARF") on behalf of both WARF and the Council on Government Relations ("COGR") (an association of 145 research-intensive universities in the United States); Mr. Kevin Rivette (attorney and author); Mr. Charles E. Van Horn (on behalf of the American Intellectual Property Law Association ("AIPLA")); and Mr. Jon Grossman (a patent attorney). A written statement was inserted in the hearing record by the American Council on Education ("ACE"). *See* Serial No. 60, 107th Cong. Several witnesses stated that the Patent Act should be amended to promote collaborative research.

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[1] 122 F.3d 1396, 43 U.S.P.Q.2d 1641 (Fed. Cir. 1997).

During the 108th Congress, the Subcommittee with an eye on solving extant problems again turned its attention to collaborative research and patent law issues. On June 9, 2003, H.R. 2391, the CREATE Act, was introduced by Subcommittee Chairman Lamar Smith and Ranking Minority Member Howard Berman and nine other Committee members (Mr. Conyers, Mr. Coble, Mr. Goodlatte, Mr. Green (of Wisconsin), Ms. Hart, Mr. Boucher, Ms. Lofgren, Mr. Wexler, and Ms. Baldwin). An additional cosponsor (Mr. Forbes) was added on June 19, 2003. On June 10, 2003, the Subcommittee held a legislative hearing on the CREATE Act, during which testimony was received from Dr. Jon Soderstrom, Managing Director, Office of Cooperative Research, Yale University (on behalf of the Association of University Technology Managers); Eric Steffe (patent attorney, Washington, DC); Jeffrey P. Kushan (patent attorney, Washington, DC); and Professor John R. Thomas, Georgetown University Law Center.

On July 22, 2003, pursuant to notice, the Subcommittee approved H.R. 2391, as amended, by voice vote and forwarded the measure to the full Committee.

BACKGROUND AND NEED FOR THE LEGISLATION

Collaborative research among private, public and non-profit entities is extremely important to the U.S. economy. In a time or terrorism and electricity grid failure, collaborations among and between professors and the private sector are increasingly critical to our country. For example, the Complex Interactive Networks/Systems Initiative ("CIN/SI"), a joint program of the U.S. Department of Defense and the Electric Power Research Institute and part of a government industry collaborative research program, is designed to develop new tools and techniques that will enable large national infrastructures to self-heal in response to threats, catastrophic failures, and other material destabilizers. Over 100 professors from 28 universities are funded. During the life of this 3-year initiative, over 360 publications have appeared and close to 20 technologies extracted.

A 1999 report of the National Research Council's Committee on Science, Engineering, and Public Policy found that partnerships among industry, academia and governments have greatly contributed to the recent technological successes in the United States, and the report recommended even stronger partnerships in the future.[2] In addition, a 1998 report by the National Science Foundation found that there had been a major increase in the number of inter-sector collaborations since the early 1980s, including more than 3,500 new cooperative research and development agreements (CRADAs) during 1992 through 1995 between and among Federal laboratories and other entities.[3] Additionally, not-for-profits and universities spent a record $23.8 billion on research and development, the majority of which came from collaborations.[4] In

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[2] "Capitalizing on Investments in Science and Technology," National Research Council, National Academy Press, 23-25; 49-51 (1999).

[3] Science and Engineering Indicators 1998, Chapter 4: U.S. and International Research and Development: Funds and Alliances, report by the National Science Foundation. http://www.nsf.gov/sbe/srs/seind98/c4/c4h.htm ["NSF Report"].

[4] *Id.*

2001, 190 reporting institutions spent $31.7 billion.[5] Sixty-three percent, or $19.9 billion, was funded by the federal government. Nine percent, or $2.78 billion, was funded by industrial sources. The income and positive effects on the U.S. economy from collaborations have been substantial. In 2001, U.S. universities, hospitals and research institutes realized approximately $1.071 billion in adjusted gross license income.[6]

The Federal patent law aggressively promotes and expressly provides for such collaborative interactions. For instance, the Bayh-Dole Act of 1980 and the Steven-Wydler Technology Innovation Act of 1980 specifically encourage and promote interaction among the public, private and non-profit sectors. Bayh-Doyle expressly identifies as one of the policy objectives of Congress "to promote collaboration between commercial concerns and non-profit organizations, including universities." 35 U.S.C. §200.

Federal laws and programs designed to promote collaborative research advance the U.S. economy and increase the rate of technological and industrial innovation. Downstream products, start-up activities and licenses are the results. The patent laws, similarly, promote collaboration among industry, university and government partners.

Why then does the current patent law chill collaboration activities? The current quandary regarding section 103 began when the U.S. Court of Customs and Patent Appeals (CCPA), the precursor to the Federal Circuit, interpreted section 103 to mean that earlier inventions made by individual members of a research team would be used under section 103 to preclude the team's invention from being patented.[7] In other words, team members employed by the same entity could not freely share information in developing an invention for fear that the shared information could preclude them from patenting a resulting technology. This interpretation greatly worried entities utilizing team research.

In response, in 1984 Congress amended section 103 by adding the current subsection 103(c) to address the problem created by the CCPA's interpretation as relates to team research *within* an organization. See Pub. L. No. 98-622, 98th Cong., 2d Sess. (1984), 98 Stat. 3383. The legislative history of the 1984 amendment clearly establishes that subsection 103(c) was designed to help encourage teamwork *within* organizations as well as among members of researchers working within corporations, universities or other organizations.[8] The issue of

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[5] AUTM Licensing Survey FY 2001, Association of University Technology Managers, Inc. (Survey Summary) available at <http://www.autm.com>.

[6] *Id.*

[7] *See, In re Bass*, 474 F.2d 1276 (CCPA 1973) and *In re Clemens*, 622 F.2d 1029 (CCPA 1980).

[8] *See* 130 Cong. Rec. 10522, 10527 (daily ed., Oct. 1, 1982), section-by-section analysis inserted in the record by Robert W. Kastenmeier. In floor debate. Rep. Kastenmeier (who served as floor manager) characterized the amendment as being broader than teamwork "within" organizations, stating that the "change will be of material benefit to university and corporate research laboratories where the free exchange of ideas and concepts may have been hampered by the current state of the law with respect to what constitutes 'prior art.'" *Id.* at H10529. The sectional analysis to the bill passed by the House confirms this proposition: "Section 104 of the bill changes a complex body of case law which discourages communication *among* members of research teams working in corporations, universities or other organizations." *Id.* At H10527.

settle the issue here (subject of course to any later intervention by Congress ...)." 122 F.3d at 1403. The court also acknowledged that its decision will be disruptive to collaborative research. The court was right.

The *Oddzon* decision is creating significant problems due to the very nature of collaborative research and development projects among universities, government labs, and industry. The unhindered flow of information among researchers within these collaborations is essential to the conduct of research, the promotion of good stewardship of the monies supporting the research effort and crucial to a successful outcome. Laws and policies that have the effect of impeding the flow of information among researchers will, for obvious reasons, have a stifling effect on the progress and success of such projects.

In short, because it is not expected that the Federal Circuit will revisit the *Oddzon* decision and the important issues raised therein, legislation – through the CREATE Act - is necessary not only to clarify the congressional intent of the 1984 amendment but also to promote collaborative research between and among universities and the private sector.

SECTION-BY-SECTION ANALYSIS

Section 1. Short Title

This Act may be cited as the "Cooperative Research and Technology Enhancement (CREATE) Act of 2003".

Section 2. Collaborative Efforts on Claimed Inventions

Section 2 enlarges the exception presently provided under subsection 103(c) of title 35, United States Code. It provides that subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f) and (g) of section 102 shall not preclude patentability where the subject matter and the claimed invention were, at the time of the earliest filing date for which a benefit is sought under this title, owned by the same person or subject to an obligation of assignment to the same person. For purposes of subsection (c), section 2 provides that subject matter and a claimed invention owned by parties to a joint research agreement shall be considered to be owned by the same person or subject to an obligation of assignment to the same person if the claimed invention arises under the terms of the joint research agreement and the agreement was entered into before the earliest filing date for which a benefit is sought.

Section 2 of H.R. 2391 defines the term "joint research agreement" as "a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention". A research collaboration, as envisioned in the legislation, could include formal written arrangements between the institutions employing the researchers (e.g., defining the scope, objectives and other parameters of a research project), as well as more limited arrangements (e.g., material transfer agreements, non-disclosure agreements) between researchers in different institutions.

A party wishing to use the Act would have to provide evidence that a qualifying collaboration existed prior to the time the invention was made. The most effective means of proving the existence of a research collaboration would be through use of documentary evidence (e.g., a contract, a cooperation agreement) that identifies the date the collaboration was established, and the parties involved in the collaboration. Thus, a material transfer agreement executed prior to or concurrent with the exchange of a biological sample would be sufficient to demonstrate the existence of a research collaboration within the meaning of this section.

The net-result of section 2 is that the treatment of information shared among researchers from different entities is equated to that of information shared among researchers employed by a single entity, or who have or are required to assign their interests to a single entity.

The CREATE Act will not promote "double patenting." A party filing an application directed to an invention that is obvious in view of the contents of an earlier filed application could not use the CREATE Act. Without the exemption, the second filed application would have to be directed to a nonobvious – and therefore independently patentable – invention.

Section 3. Effective date

Section 3 sets the effective date of the amendments made by the Act. Its language parallels that of the 1984 amendment that created section 103(c). Subsection (a) provides the general applicability of the amendment and states it applies to all U.S. patents granted before, on or after the date of enactment. Subsection (b) defines exceptions to the general applicability of subsection (a). According to subsection (b), the amendments made by the Act will not affect any final decision that has been rendered by a court or the U.S. Patent and Trademark Office before the date of enactment. Subsection (b) also establishes that the amendments made by the Act shall not affect the rights of any party in any action pending before the U.S. Patent and Trademark Office or a court on the date of enactment to have that party's rights determined on the basis of the provisions of the Patent Act in effect on the day before the date of enactment. In short, H.R. 2391 is not retroactive.

SUPPORTERS

1. Wisconsin Alumni Research Foundation (WARF)
2. American Council on Education (ACE)
3. National Association of State Universities and Land Grant Colleges (NASULGC)
4. Association of American Universities (AAU)
5. Genentech

October 7, 2003

THE COOPERATIVE RESEARCH AND TECHNOLOGY ENHANCEMENT (CREATE) ACT OF 2003
H.R. 2391

- COLLABORATIVE RESEARCH – THE ENGINE FOR SCIENTIFIC PROGRESS. Partnerships among industry, academia and government (state and federal) have greatly contributed to recent technological successes in the United States. In an era of terrorism and electrical infrastructure network failure, collaborative research activities become more important. The American public – be it patients who benefit from biotechnology advances and pharmaceutical breakthroughs, farmers who depend on agricultural and veterinary discoveries, or the consumer who has a broad choice of new products – is the beneficiary.

- THE SWORD OF DAMOCLES. A 1997 decision of the U.S. Court of Appeals for the Federal Circuit (*Oddzon Products, Inc. v. Just Toys, Inc.* 122 F.3d 1396) hangs like the proverbial sword of Damocles over collaborative research efforts. That decision is viewed as creating a significant threat to the loss of intellectual property rights for inventors who engage in joint research and development projects with scientists not employed by the same entity whether located in academia, industry or elsewhere.

  The essence of the *Oddzon* decision was that researchers who enter into a well-defined and structured research collaboration BUT WHO DO NOT AT THAT TIME TRANSFER THEIR RIGHTS TO BACKGROUND TECHNOLOGY ON WHICH THE COLLABORATION IS BASED AND RIGHTS IN FUTURE INVENTIONS TO A SINGLE ENTITY can create obstacles to obtaining or enforcing a patent on an invention that is generated during the course of the collaboration. THE INFORMATION DOES NOT HAVE TO BE PUBLICLY DISCLOSED OR COMMONLY KNOWN. All that is required is that the collaborators exchange the information without first designating COMMON OWNERSHIP of the information or of any invention that may arise from the collaboration. The *Oddzon* decision is especially damaging to non-profits; including universities and research institutes, which perform a very large percentage of basic research in this country.

- SUPPORT THE CREATE ACT. H.R. 2391, the CREATE Act, was introduced by Representatives Lamar Smith and Howard Berman (Chairman and Ranking Minority Member of the House Judiciary Subcommittee on Courts, the Internet, and Intellectual Property) and is cosponsored by a bipartisan group of ten other members of the House Committee on the Judiciary (Mr. Coble, Mr. Goodlatte, Mr. Green (of Wisconsin), Ms. Hart, Mr. Forbes, Mr. Conyers, Mr. Boucher, Ms. Lofgren, Mr. Wexler, and Ms. Baldwin). Further cosponsors are being sought. The CREATE ACT solves the underlying problems in the patent law.

- CONGRESS IS THE SOLE FORUM TO RESOLVE THIS POLICY ISSUE. The *Oddzon* decision was a strict construction of the patent law. The court itself invited Congress to review the underlying patent law: "It is sometimes more important that a close question be settled one way or another than which way it is settled. We settle the issue here (subject of course to any late intervention by Congress...)."

- THE CREATE ACT IS CONSISTENT WITH THE PATENT ACT. The Federal patent law aggressively promotes and expressly contemplates collaborative interactions. For example, the Bayh-Dole Act (regarding patent rights in inventions made with Federal assistance) and the Stevenson-Wydler Technology Innovation Act of 1980 specifically encourage and promote interaction among the public, private and non-profit sectors. The Bayh-Dole Act expressly identifies the policy and objective of the U.S. Congress as being to "promote collaboration between commercial concerns and nonprofit organizations, including universities."

UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

NOV 20 2003

The Honorable Ted Stevens
Chairman, Committee on Appropriations
United States Senate
Washington, DC 20510-6025

Dear Mr. Chairman: Ted —

Thank you for the opportunity to present the Administration's position on the Weldon amendment adopted by the House during consideration of H.R. 2799, the Commerce-Justice-State Appropriations bill FY 2004, and the effect it would have on the United States Patent and Trademark Office (USPTO) policy on patenting living subject matter. For the reasons outlined below, we view the Weldon amendment as fully consistent with USPTO's policy on the non-patentability of human life-forms.

The Weldon Amendment would prohibit the U.S. Patent and Trademark Office from issuing any patent "on claims directed to or encompassing a human organism." The USPTO understands the Weldon Amendment to provide unequivocal congressional backing for the long-standing USPTO policy of refusing to grant any patent containing a claim that encompasses any member of the species Homo sapiens at any stage of development. It has long been USPTO practice to reject any claim in a patent application that encompasses a human life-form at any stage of development, including a human embryo or human fetus; hence claims directed to living "organisms" are to be rejected unless they include the adjective "nonhuman."

The USPTO's policy of rejecting patent application claims that encompass human life-forms, which the Weldon Amendment elevates to an unequivocal congressional prohibition, applies regardless of the manner and mechanism used to bring a human organism into existence (e.g., somatic cell nuclear transfer, in vitro fertilization, parthenogenesis). If a patent examiner determines that a claim is directed to a human life-form at any stage of development, the claim is rejected as non-statutory subject matter and will not be issued in a patent as such.

As indicated in Representative Weldon's remarks in the Congressional Record of November 5, 2003, the referenced language precludes the patenting of human organisms, including human embryos. He further indicated that the amendment has "exactly the same scope as the current USPTO policy," which assures that any claim that can be

broadly construed as a human being, including a human embryo or fetus, is not patentable subject matter. Therefore, our understanding of the plain language of the Weldon Amendment is fully consistent with the detailed statements that the author of the amendment, Representative Weldon, has made in the Congressional Record regarding the meaning and intent of his amendment.

Given that the scope of Representative Weldon's amendment does not alter the USPTO policy on the non-patentability of human life-forms at any stage of development and is fully consistent with our policy, we support its enactment.

With best personal regards, I remain

Sincerely,

JAMES E. ROGAN
Under Secretary and Director

cc: The Honorable Robert C. Byrd
The Honorable Judd Gregg
The Honorable Ernest F. Hollings

Specifically, this language request that the FAA seriously review the potential of transferring the U.S. military's deployable flight data recorder technology into our commercial air fleet.

I am very pleased that this language was included as it reflects the goals I am seeking to implement within the legislation that I introduced earlier this year, H.R. 2632, the Safe Aviation Flight Enhancement (SAFE) Act.

Congress has previously showed interest in the deployable technology and requested within the FY2001 Transportation Appropriations Bill, that the FAA issue a report to Congress on the benefits and advisability of using deployable flight recorders in the commercial fleet. This report was issued in the December 4, 2001 Future Flight Data Collection Committee Final Report and detailed the United States military's successful use of the deployable recorder technology, concluding that it would be acceptable to incorporate the deployable recorder technology within the NTSB's 1999 recommendation to improve flight recorder standards.

The 1999 NTSB recommendations that the FAA's report is referring to were issued as a result of a history of delay in black box recovery and lost data due to crash damages in some of our countries most recent and devastating air accidents.

Following a series of air accidents where critical flight recorder information was lost, the NTSB issued recommendations A–99–16 through 18, which called on the FAA to require improved recorder capabilities and the installation of two sets of combination flight data and cockpit voice recorders in commercial aircraft to ensure the survival and recovery of at least one set of recorders.

It is important to note that the intention of the Conferee's language on deployable recorders within the FAA, operations section of the FY2004 Omnibus appropriations conference report is that the FAA evaluate the deployable technology within the context of incorporating the deployable recorder system as one of the two combination recorder systems recommended in the NTSB's 1999 recommendations.

I am hopeful that the FAA will move swiftly on this, since 4 years have passed and these recommendations have yet to be addressed.

The terrorist attacks of 9/11 opened the Nation's eyes to the face that our skies are vulnerable to more than mechanical or human error. One of our best examples of what can occur when we do not have immediate access to this information following a crash was demonstrated in the aftermath of the TWA 800 crash. This accident clearly illustrated the pressures investigators are under to rule out the potential of terrorism and quickly identify the safety concerns. At the outset of TWA 800 crash investigation, there was intense speculation that a ground-to-air missile was the cause of this disaster. For every day that went by as we search the ocean floor for the recorders, the speculation and questions mounted about the potential of terrorism. Ultimately, it took 7 days and millions of dollars to recover those fight recorders from the bottom of the ocean and eventually, investigators and explosive's experts led us to the understanding that it was an accidental fuel tank explosion, not terrorism that was responsible for the crash.

Post 9/11, we cannot afford to be faced with a similar situation of uncertainty. Our national security teams and transportation safety officials must have immediate access to the flight recorders to determine the appropriate response.

The deployable technology presents us with ability to ensure immediate and complete access to the flight recorders today, as our United States Navy has successfully tested, developed and used the deployable recorder technology for years on aircraft including the Navy's F/A–18EF Super Hornet fleet. The deployable technology is capable of meeting the needs of the commercial industry and is designed to "deploy" from the aircraft during a accident, which allows it to land outside of the crash impact site, thus avoiding becoming ensnared within the aircraft wreckage and the direct impact forces and fire intensity of the crash. The deployable recorder is also designed to float indefinitely in cases of a water crash.

The use of the deployable recorder in the commercial air fleet would provide the same benefits that it does for the military and would present an obvious way to maximize our ability to ensure the survivability and quick recoverability of flight recorders.

Again, I am pleased that Congress addressed this very important issue to encourage the FAA to move expeditiously in formulating regulations to address the need for improved flight recorders and that Congress would like the deployable technology to be considered within the context of the dual-combination recorder recommendation issued by the NTSB in 1999.

Such improvements will help us ensure that our safety and security officials will have immediate and complete access to the recorders following an aviation crash and make great strides in protecting the American people.

★ Mr. WELDON of Florida. Mr. Speaker, on July 22, 2003, I introduced an amendment to provide congressional support for the current U.S. Patent and Trademark Office (USPTO) policy and practice against approving patent claims directed to human organisms, including human embryos and human fetuses. The House of Representatives approved the amendment without objection on July 22, 2003, as section 801 of the Fiscal Year 2004 Commerce/Justice/State Appropriations Bill. The amendment, now included in the Omnibus appropriations bill as section 634 of H.R. 2673, reads as follows: "None of the funds appropriated or otherwise made available under this Act may be sued to issue patents on claims directed to or encompassing a human organism."

The current Patent Office policy is that "non-human organisms, including animals" are patentable subject matter under 35 U.S.C. 101, but that human organisms, including human embryos and human fetuses, are not patentable. Therefore, any claim directed to a living organism must include the qualification "non-human" to avoid rejection. This amendment provides unequivocal congressional support for this current practice of the U.S. patent office.

House and Senate appropriators agreed on report language in the manager's statement on section 634. The statement reads: "The conferees have included a provision prohibiting funds to process patents of human organisms. The conferees concur with the intent of this provision as expressed in the colloquy between the provision's sponsor in the House and the ranking minority member of the House Committee on Appropriations as occurred on July 22, 2003, with respect to any existing patents on stem cells."

The manager's statement refers to my discussion with Chairman DAVID OBEY, when I explained that the amendment "only affects patenting human organisms, human embryos, human fetuses or human beings." In response to Chairman OBEY's inquiry, I pointed out that there are existing patents on stem cells, and that this amendment would not affect such patents.

Here I wish to elaborate further on the exact scope of this amendment. The amendment applies to patents on claims directed to or encompassing a human organism at any stage of development, including a human embryo, fetus, infant, child, adolescent, or adult, regardless of whether the organism was produced by technological methods (including, but not limited to, in vitro fertilization, somatic cell nuclear transfer, or parthenogenesis). This amendment applies to patents on human organisms regardless of where the organism is located, including, but not limited to, a laboratory or a human, animal, or artificial uterus.

Some have questioned whether the term "organism" could include "stem cells". The answer is no. While stem cells can be found in human organisms (at every stage of development), they are not themselves human organisms. This was considered the "key question" by Senator HARKIN at a December 2, 1998 hearing before the Senate Appropriations Subcommittee on Labor, Health and Human Services and Education regarding embryonic stem cell research. Dr. Harold Varmus, then director of the NIH testified "that pulripotent stem cells are not organisms and are not embryos . . ." Senator HARKIN noted: "I asked all of the scientists who were here before the question of whether or not these stem cells are organisms. And I believe the record will show they all said no, it is not an organism." Dr. Thomas Okarma of the Geron Corporation stated: "My view is that these cells are clearly not organisms . . . in fact as we have said, are not the cellular equivalent of an embryo." Dr. Arthur Caplan agreed with this distinction, saying that a stem cell is "absolutely not an organism." There was a unanimous consensus on this point at the 1998 hearing, among witnesses who disagreed on many other moral and policy issues related to stem cell research.

The term "human organism" includes an organism of the human species that incorporates one or more genes taken from a non-human organism. It includes a human-animal hybrid organism (such as a human-animal hybrid organism formed by fertilizing a non-human egg with human sperm or a human egg with non-human sperm, or by combining a comparable number of cells taken respectively from human and non-human embryos). However, it does not include a non-human organism incorporating one or more genes taken from a human organism (such as a transgenic plant or animal). In this respect, as well, my amendment simply provides congressional support for the Patent Office's current policy and practice.

This amendment should not be construed to affect claims directed to or encompassing subject matter other than human organisms, including but not limited to claims directed to or encompassing the following: cells, tissues, organs, or other bodily components that are not

themselves human organisms (including, but not limited to, stem cells, stem cell lines, genes, and living or synthetic organs); hormones, proteins or other substances produced human organisms; methods for creating, difying, or treating human organisms, including but not limited to methods for creating human embryos through in vitro fertilization, somatic cell nuclear transfer, or parthenogensis; drugs or devices (including prosthetic devices) which may be used in or on human organisms.

Jamed Rogan, undersecretary of the U.S. Patent and Trademark Office, has stated in a November 20, 2003, letter to Senate appropriators: "The USPTO understands the Weldon Amendment to provide unequivocal congressional backing for the long-standing USPTO policy of refusing to grant any patent containing a claim that encompasses any member of the species Homo sapiens at any stage of development . . . including a human embryo or human fetus . . . The USPTO's policy of rejecting patent application claims that encompass human lifeforms, which the Weldon Amendment elevates to an unequivocal congressional prohibition,, applies regardless of the manner and mechanism used to bring a human organism into existence (e.g., somatic cell nuclear transfer, in vitro fertilization, parthenogenesis)." Undersecretary Rogan concludes: "Given that the scope of Representative WELDON's amendment . . . is full consistent with our policy, we support its enactment."

The advance of biotechnology provides enormous potential for developing innovative science and therapies for a host of medical needs. However, it is inappropriate to turn scent individuals of the human species into itable commodities to be owned, licensed, marketed and sold.

Congressional action is needed not to change the Patent Office's current policy and practice, but precisely to uphold it against any threat of legal challenge. A previous Patent Office policy against patenting living organisms in general was invalidated by the U.S. Supreme Court in 1980, on the grounds that the policy has no explicit support from Congress. In an age when the irresponsible use of biotechnology threatens to make humans themselves into items of property, of manufacture and commerce, Congress cannot let this happen again in the case of human organisms.

I urge my colleagues to support this Omnibus in defense of this important provision against human patenting.

Mr. WAXMAN. Mr. Speaker, I rise today to discuss the privatization provisions of this bill, provisions that govern when federal jobs are given to private contractors under an obscure Office of Management and Budget (OMB) Circular called A–76.

It is becoming increasingly clear that the Bush administration has declared war on federal employees. Under the guise of reform, it has stripped hundreds of thousands of federal employees of basic rights, like the right to appeal unfair treatment and the right to collective bargaining. It has opposed modest cost-of-living increases for rank and file employees while at the very same time supporting large h bonuses for political employees.

ut the Administration's most direct assault federal employees is the effort to terminate federal jobs and hire private companies to perform the same work. The President's "Competitive Sourcing Initiative" is aggressively forcing federal agencies to allow private contractors to bid for hundreds of thousands of jobs currently being performed by federal employees. Earlier this year, the Administration rewrote the rules governing competitions between public employees and private sector contractors.

The House is on record as rejecting those new rules because those rules so blatantly favored contractors over federal employees. And on a bipartisan basis, appropriations conferees last month agreed to certain basic protections for all federal employees. Unfortunately, after the conference was closed on the Transportation Treasury Appropriations bill, OMB registered last minute objections, and the Republican leadership rewrote the bill to eliminate or truncate those basic protections for federal workers.

For example, the bill, before us no longer includes language giving federal employees the right to contest agency competitive sourcing decisions, and it no longer even requires that an agency achieve significant cost savings on all privatizations. Mr. Speaker, it is time to end the assault on federal workers. Vote no on this bill. We can do better.

Mrs. McCARTHY of New York. Mr. Speaker, like many of my colleagues, I have concerns with numerous provisions in this omnibus bill. Among them are three that may actually contribute to violent crime in our communities and aid terrorists. These NRA-backed provisions were added in the dead of night to the benefit of gun manufacturers and criminals who obtain guns illegally.

The first weakens the highly successful Brady Bill by requiring federal authorities to destroy all firearm purchase records within 24 hours instead of 90 days as under current law. This provision weakens law enforcement's ability to stop illegal gun purchases and rejects a July 2002 GAO study which concluded that a "next-day destruction policy . . . would have public safety implications and could lessen the efficacy of current operations." Nearly one million illegal gun purchases have been stopped since the Brady law went into effect. Now is not the time to tie the hands of law enforcement officials who tirelessly work to keep guns out of the hands of criminals.

Another provision would protect "bad apple" gun dealers. For example, the snipers who terrorized Maryland, Virginia, and Washington, D.C. obtained the assault rifle used in their sniper attacks from a Tacoma, Washington gun store called Bull's Eye Shooter Supply. After the sniper suspects were apprehended and the gun was recovered and traced, Bull's Eye claimed to have no record of selling the gun, and did not even know it was missing until the shooting spree was over. The snipers' gun was just one of more than 238 firearms "missing" from Bull's Eye's inventory during the previous three years.

This provision would essentially block ATF from requiring gun dealers like Bull's Eye to take regular inventories of their firearms. In August 2000, ATF issued a proposed rule requiring licensed dealers to do annual physical inventories. The rulemaking proceeding is still pending. If anything, Congress should require ATF to issue this rule. Instead, this legislation would block ATF from ever issuing this requirement as a final rule. This would severely hamstring ATF's ability to address what it has stated is a serious problem.

And lastly, language was included to prevent public scrutiny of corrupt gun dealers.

ATF has indicated analysis of crime gun traces and multiple sale reports has yielded a series of gun "trafficking indicators" that can be linked to particular firearms dealers.

ATF has always made this information available to the public through Freedom of Information Act ("FOIA") requests, which allow for vital public oversight of the effectiveness of the Agency. Under the provision in the omnibus appropriations bill, ATF will not be allowed to release trace or multiple sale data, thereby gutting the purposes of FOIA, and effectively shielding the most corrupt firearms dealers from public scrutiny.

The NRA lobbied hard for these favors which do nothing to keep American families safe, but rather advance another well-connected special interest. Worse, they could actually contribute to more illegal gun purchases, meaning more criminals with guns.

We should be working to prevent firearms from falling into the wrong hands. Instead, this Administration and Congressional leadership continues to roll back commonsense gun safety measures that save lives. We can, and must, do better.

Ms. JACKSON-LEE of Texas. Mr. Speaker, the House will consider the conference report on H.R. 2673, the Agriculture Appropriations bill for FY 2004. This has become the omnibus spending bill for enacting the remaining seven appropriations bills—Agriculture, VA–HUD, Labor-HHS, District of Columbia, Commerce-Justice-State, Foreign Operations, and Treasury-Transportation. The bill would fund, for the fiscal year that began two months ago, 11 of the 15 Cabinet departments, several independent government agencies, and the District of Columbia government—and makes up $328 billion of the total discretionary budget for the year. Currently, these departments are operating under a continuing resolution funding the government through January 31, 2004.

This measure is not only an irresponsible way to govern, but more importantly it represents misplaced priorities. This session of Congress has proven again that Republican policies are making it harder for Americans to succeed. Democrats want to put American families first. We will continue to fight to create jobs, make health care more affordable, honor our veterans, and return America to prosperity. The following highlights some of the deficiencies of the omnibus bill.

This measure excludes a provision to block Bush Administration regulations that would deny overtime pay to 8 million employees. This provision to protect the pay of middle-income Americans was agreed upon by a majority of both bodies, and yet was dropped in the backroom deals at the 11th hour at the insistence of the Bush Administration. At a time when people are working harder and longer just to make ends meet, this measure permits a cut in the pay of millions of workers, including firemen and policemen, licensed practical nurses, and air traffic controllers.

Even though education is a top priority of the American people, this measure provides $39 million less for education than the inadequate House bill, after subtracting the $318 million in earmarked projects added in conference. This measure fails to meet the promised education investment promised in the No Child Left Behind Act—providing $7.8 billion

H

AUTM™

Association of University Technology Managers

AUTM Licensing Survey: FY 2002

Survey Summary

A Survey Summary of Technology Licensing (and Related) Performance for U.S. and Canadian Academic and Nonprofit Institutions, and Patent Management and Investment Firms

Dear AUTM Members and Colleagues,

Since its inception more than a decade ago, the *AUTM Licensing Survey*™ has become the gold standard for data on the transfer of academic research for commercial application.

And for good reason. Often cited in publications around the globe, the *Licensing Survey* is the most comprehensive of its kind, providing quantitative information on licensing activities from U.S. and Canadian universities, hospitals and research institutions. With this data, AUTM members, legislators, government agencies, policy makers, media representatives and others are able to glimpse the many ways technology transfer impacts all facets of society. They can see trends in these impacts spanning over a decade. In recognition of the importance of the information it generates, the methodology of the *AUTM Licensing Survey*™ is just now starting to be replicated in other leading innovation economies throughout the world. The data also allow us to peer into the future by looking at the trends in licensing and product development.

The *FY 2002 Licensing Survey*™ is no exception. With 222 respondents, the *FY 2002 Licensing Survey* collected data from more organizations than ever before, 24 more institutions than last year. These organizations reported:

- Five hundred sixty-nine new commercial products were launched, bringing the total number of new products introduced into the marketplace since fiscal year 1998 to well over 2,000;
- Four hundred fifty new companies were established in fiscal year 2002, for a total of 4,320 since 1980;
- Two thousand seven hundred forty-one of those start-ups were still operating as of the end of fiscal year 2002;
- Running royalties on product sales were $1.005 billion, a 18.9 percent increase over fiscal year 2001; and
- New licenses and options executed in fiscal year 2002 increased 15.2 percent from fiscal year 2001, reversing a downward trend since fiscal year 2000.

Of course, as mere numbers, these data tell only part of the story. And with such a diverse pool of respondents, the statistics provided are not directly comparable from one institution to another. But despite these caveats, one irrefutable theme emerges: The mission of technology transfer is permeating all parts of academia. From the smallest colleges to the largest universities and leading research facilities, organizations are creating the infrastructure to translate the fruits of their research into products that serve the public good. And that's one measure of success that is unquantifiable.

On behalf of the AUTM Board of Trustees and the entire AUTM membership, congratulations and kudos to the Survey, Statistics and Metrics Committee, led by Boston University's Ashley Stevens, for another superb effort.

Thank you also to all the supporting institutions for your continued effort and support. We couldn't do it without you.

Patricia Harsche Weeks
2003–2004 AUTM President

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AUTM Licensing Survey™: FY 2002

Survey Summary

Edited By: Ashley J. Stevens, D. Phil (Oxon), Chairman
AUTM Survey, Statistics and Metrics Committee

The Association of University Technology Managers (AUTM) has undertaken this Survey and is reporting the results herein for the educational benefit of its own members and as a public service to government at the federal, state and local levels, the public, the nonprofit technology licensing community and other stakeholders in the technology commercialization process. AUTM has assembled these data, including product stories, using responses obtained from its members representing educational and other nonprofit research organizations. The contributors to the data and product vignettes voluntarily reported their results to AUTM using the AUTM Licensing Survey instrument. AUTM has made no independent verification of the data presented herein. The data is reported herein on an "as reported" basis.

AUTM Licensing Survey

The *AUTM Licensing Survey* was prepared by the AUTM Survey, Statistics and Metrics Committee.

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Copies of the Report

Information on the price and availability of the FY 2002 Survey Summary or the Full Report may be obtained on the AUTM Web site at www.autm.net or by contacting:

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For response to inquiries on the data, please contact Ashley Stevens, Survey, Statistics and Metrics Committee Chair, preferably by e-mail at astevens@bu.edu or by phone at (617) 353-4550.

Acknowledgements

It has been a privilege to be associated with the preparation of this report. I thank all current members of the Survey, Statistics and Metrics Committee. Special thanks are due to my predecessor as chair, Lori Pressman, who has been a rock solid source of institutional memory, information and support, and an invaluable sounding board. Joyce Brinton is always the first to respond to requests for input, advice and help.

In addition, this is a unique opportunity to thank Robin Rasor who is a close friend, a valued colleague, an ever available source of counsel and advice, a tireless worker for AUTM, a fearless rejecter of "We've always done it that way" and perhaps most important an impassioned advocate for the Survey within AUTM. The conversion to Web-based entry, one of the great advances in the Survey, was her idea. She managed from the right distance, asking the big questions not the little ones, and her corrections, comments and advice were always there when I needed them.

Special thanks are due to John Fraser and the members of the Social Impact Analysis Subcommittee of the Survey, Statistics and Metrics Committee: Allyson Best, Dave King, Doug Jamison, Herb Winfield, James Lancaster, Jeff Cope, Jill Loren-Gold, Jim Hardy, Laurel Halfpap, Marie-Christine Piriou, Mark Laurenzo, Ray Hoemsen, Sara Jane Lee, Tom Walsh and Trina Nealy, who worked with the various institutions who expressed a desire to have the stories of their products told.

I acknowledge with gratitude many helpful discussions with Ajay Vohora of the Nottingham University Business School which carries out the excellent U.K. study of academic technology transfer activity, now in its second year and is based on AUTM's methodology and definitions.

The current committee wishes especially to recognize and thank Rick and Nola Colman for their Herculean efforts in dragging the Survey kicking and screaming into the Internet age by moving it from a paper submission of data to electronic submission. The improvements in speed and accuracy that have resulted from this change will be an enduring legacy to AUTM.

This report would not exist if not for the directors of the institutions' technology transfer offices and their staff who have diligently gathered and submitted data over the past twelve years. The Survey is only as good as the effort that AUTM's members put into collecting and reporting their institutions' data. The Survey, Statistics and Metrics Committee, speaking for the Board of AUTM and all the members of AUTM, recognizes this effort, which is never part of their job descriptions but represents a considerable extra effort and labor of love, and expresses its gratitude to them on behalf of the membership for their considerable efforts.

I thank, as ever, Janine Anderson, my patent paralegal for her conscientious proof reading. No important document leaves my office without her imprimatur.

Finally, we thank our readers, and invite them to read the social impact analyses, the stories of individual projects, passions and efforts by teams of people working towards an elusive and far-off goal and which represent the ultimate justification for our profession and the effort we all put into it.

Ashley J. Stevens
Chairman, AUTM Survey, Statistics and Metrics Committee

Introduction and Overview

The phrase "technology transfer" can be used very broadly to describe the movement of ideas, tools, and people among institutions of higher learning, the commercial sector, and the public. This report focuses on how AUTM members manage intellectual property to make the results of academic research available to the public in the form of commercial products. The reader can find quantitative information on various technology transfer parameters in this report, such as the number of patents issued to universities, the number of license/option agreements executed by academic institutions, and the like. Additionally, short summaries of the social impact of a few specific products are found in Sections 1 and 5. Much more detail on these and other products are available on AUTM's Web site at www.autm.net.

AUTM surveys its members annually and has collected data for each fiscal year beginning with fiscal year 1991. A full account of the Survey Methodology is presented in Attachment C, on page 40. The precise meaning of each of the data elements measured in the Survey will be found there. These definitions are important to the interpretation of reported data and, in general, provide a glossary of terms recognized by the academic technology transfer community. Additional charts and tables are published in the Full Report (See page 39). In general, the definitions used by AUTM are the foundation of reports on technology transfer that are starting to be generated in technologically advanced countries around the world.

The statistics provided in this Survey Summary may not be directly comparable from one institution to another, in light of the autonomous stature of each institution, and the significant cultural variations between institutions. Some institutions are land grant universities with unique missions; some institutions have teaching/research hospitals while others do not; and some institutions are located in rural communities with little entrepreneurial infrastructure. However, one of the themes that emerges in the Survey, reflected in the dramatic increase in AUTM's membership from 1,015 in 1993 when the Survey started to 3,055 at the start of AUTM's 2003 fiscal year, is how the mission of technology transfer is permeating all parts of academia. Even the smallest colleges and universities are creating the infrastructure to translate the fruits of their research into products that serve the public good.

Therefore some survey respondents are reporting the results of mature programs, while others are reporting the results of relatively new programs. Since the technology transfer process takes place over many years, data from programs at different points in the process are not readily comparable.

This report does not attempt to analyze the data it generates. That is left to the numerous academic economists, policy specialists, lawyers, ethicists and others who take this data and delve into it to elucidate its underlying causality and implications. We report the facts and leave others to speculate on the causes and implications.

Table of Contents

AUTM Licensing Survey

Executive Summary

This publication marks the twelfth year for which the Association of University Technology Managers (AUTM) has collected data on licensing activities from its academic constituency, including data from U.S. universities, hospitals, nonprofit research institutions, and patent management and investment firms as well as from Canadian institutions. Two hundred and twenty-two (222) U.S. and Canadian universities, teaching hospitals, research institutes and patent management and investment firms responded to the Survey, an increase of 24 over fiscal year 2001.

One hundred and forty-one (141) institutions indicated that 569 new commercial products were introduced to the marketplace in fiscal year 2002 under license agreements with commercial partners. Since fiscal year 1998 when the question was first asked, 164 U.S. and Canadian survey respondents have reported a total of 2,076 new products introduced to the market place.

Research Expenditures

- Total fiscal year 2002 sponsored research expenditures were $37.018 billion reported by 212 institutions, up 16.6% from $31.760 billion reported by 194 institutions in fiscal year 2001.
- Total fiscal year 2002 sponsored research expenditures funded by federal government sources were $23.118 billion reported by 206 institutions, up 15.9% from $19.940 billion reported by 192 institutions in fiscal year 2001.
- Total fiscal year 2002 sponsored research expenditures funded by industry were $2.974 billion reported by 199 institutions, up 6.8% from the $2.784 billion reported by 189 institutions in fiscal year 2001.

Patent-Related Activity

- 15,573 Invention Disclosures were reported in fiscal year 2002 by 221 institutions, up 14.8% from 13,569 reported by 196 institutions in fiscal year 2001.
- 7,741 New U.S. Patent Applications were filed in fiscal year 2002 by 216 institutions, up 13.6% from 6,812 reported by 195 institutions in fiscal year 2001.
- 3,673 U.S. Patents Issued in fiscal year 2002 reported by 219 institutions, down 1.3% from the 3,721 issued in fiscal year 2001 reported by 195 institutions, bringing the total number of U.S. Patents Issued reported in the Survey to 28,093 since fiscal year 1993, the first year for which data were collected on U.S. Patents Issued.

Licenses and Options

- 4,673 new licenses and options were executed in fiscal year 2002 reported by 219 institutions, up 15.2% from 4,058 in fiscal year 2001 reported by 197 institutions and reversing the decrease between fiscal year 2000 and fiscal year 2001 noted in last year's report.
- 26,086 licenses and options were active in fiscal year 2002 reported by 217 institutions, up 13.7% from 22,937 in fiscal year 2001 reported by 192 institutions. Respondents reported receiving Running Royalties on product sales from 22.4% of these active agreements.
- Of the 4,594 licenses and options executed in fiscal year 2002 characterized by type of exclusivity (98.3% of the total reported licenses and options) 46.5% of new licenses and options executed were exclusive and 53.5% were non-exclusive, compared with the 48.0% exclusive: 52.0% non-exclusive breakdown reported in fiscal year 2001 and 50.3% exclusive:49.7% non-exclusive reported in fiscal year 2000.
- For the 4,509 licenses and options executed in fiscal year 2002 for which data on both exclusivity type and the size and nature of the licensee was reported (96.5% of the total reported licenses and options):
  - 68.2% of new licenses and options executed were with newly formed or existing small companies (fewer than 500 employees), while 31.8% were with large companies;
  - 91.0% of licenses and options to start-ups were exclusive;
  - 45.4% of licenses to existing small companies were exclusive; and
  - 38.7% of licenses to large entities were exclusive.

License Income

- 10,866 licenses/options yielded income of some sort in fiscal year 2002 reported by 218 institutions, up 11.9% from 9,707 in fiscal year 2001 reported by 194 institutions;
- 5,853 licenses/options generated running royalties on product sales in fiscal year 2002 reported by

Two hundred twenty-two (222) institutions participated in the Survey in fiscal year 2002 and 198 institutions responded in fiscal year 2001. See page 30 for more information on participants.

Terms from the AUTM Survey are shown capitalized and are defined in Attachment C, on page 40. Notes, i.e., i–xxii, appear throughout the report and may be found on pages 33–35.

215 institutions, up 15.1% from 5,085 in fiscal year 2001 reported by 179 institutions;
- Gross license income received from licenses and options in fiscal year 2002, after elimination of double counting, was $1.267 billion reported by 218 institutions, up 18.3% from $1.071 billion in fiscal year 2001 reported by 198 institutions.
- Running Royalties on product sales in fiscal year 2002 were $1.005 billion reported by 212 institutions, up 18.9% from $844.9 million in fiscal year 2001 reported by 192 institutions.

Start-Up Activity

- 450 new companies based on an academic discovery were formed in fiscal year 2002 reported by 214 institutions, down 8.9% from 494 start-ups reported by 195 institutions in fiscal year 2001. 83.1% of the new companies were located in the state/province of the academic institution where the technology was created.
- Since 1980, 4,320 new companies have been formed based on a license from an academic institution, including the 450 established in fiscal year 2002.
- 2,741 of these start-ups were still operating as of the end of fiscal year 2002.
- Academic institutions received an equity interest in 69.6% of their start-ups in fiscal year 2002, compared to 70.4% in fiscal year 2001.

1.0 New Products and Technologies Resulting from U.S. Licensing Activities

One hundred and twelve respondents identified 569 products that were first made commercially available to the public in fiscal year 2002, bringing to 2,076 the total number of products made commercially available by survey respondents in fiscal years 1998 – 2002. The number of new products introduced in fiscal year 2002 is up 211 or 58.9% from the number introduced in fiscal year 2001. Following are several samples illustrating the social impact of products developed out of U.S. university research. Examples of new products introduced in Canada are found on page 27. For additional information on these products and on products that resulted from academic research in previous years, visit the AUTM Web site at www.autm.net.

Health

SpeechEasy® — East Carolina University

Traditional therapy for the 60 million stutterers worldwide consists of years of behavioral modification and provides limited long-term efficacy. Drs. Joseph Kalinowski, Andrew Stuart and Michael Rastatter, in the Department of Communication Sciences and Disorders at East Carolina University have developed a patented (U.S. Patent 5,961,443) prosthetic device, SpeechEasy®, which provides stutterers with the first mobile, inconspicuous wireless device that virtually eliminates stuttering through the use of delayed auditory and frequency altered feedback.

In July 2001, ECU start-up company Janus Development Group exclusively licensed the rights to SpeechEasy® and sold the first device in August 2001. More than 1,000 people have benefited from SpeechEasy® with dramatic results. Users report entire lifestyle changes in daily living and their ability to set long-term goals. In addition to scholarly publications, SpeechEasy® has been featured numerous times in the press including on ABC's Good Morning America, which received an Emmy award for its moving story. (www.speecheasy.com)

Partners for a Healthy Baby Curriculum — Florida State University

Over the past five years the Florida State University Center for Prevention and Early Intervention Policy, under the leadership of Dr. Mimi Graham, has developed, copyrighted and widely distributed "The Partners for a Healthy Baby" curricular series.

These research-based guides were developed to help home visitors conduct visits to help expectant families have, and then cope with, a new baby to ensure a happy, healthy baby. Critical topics are designed for each trimester/month of pregnancy until the baby's first birthday. Magazine style handouts reflecting ethnically diverse families are given to parents in both English and Spanish. (see http://www.cpeip.fsu.edu/).

These curricula, unique in addressing both the family and the child's health and development, are enthusiastically utilized by "Early Head Start," "Healthy Start Healthy Families" programs, hospitals and school boards throughout the nation.

In fiscal year 2002, cumulative sales surpassed $3 million. New "Fatherhood" and "Self-Esteem" curricula are ready for printing.

Oragenics Completes Initial Public Offering — University of Florida

Oragenics Inc. is developing two technologies licensed from the University of Florida. The first, developed by Professor Jeffrey Hillman, is a replacement therapy for the prevention of tooth decay, consisting of a simple and painless mouth rinse administered by a dentist to protect against cavities for a lifetime. Replacement therapy may be the most significant advance in dental care and cavity prevention since the introduction of fluoride more than half a century ago.

The second novel technology is a broad-spectrum antibiotic (mutacin 1140), which holds the promise of offering protection against a wide variety of disease-causing bacteria. Preliminary laboratory studies of this novel antibiotic show no evidence of pathogen resistance, which has become a major problem with the six leading classes of antibiotics in use today.

Oragenics, a Florida-based biotechnology company, announced the successful completion of its $3 million initial public offering on June 24, 2003.

Fel-O-Vax — Protecting Cats Against FIV — University of California, Davis and University of Florida

As many as one in twelve cats tests positive for the feline immunodeficiency virus (FIV), a deadly and rapidly spreading virus that, like its human counterpart (HIV), weakens the cat's immune system to the point that it can no longer fight off infection or disease. Transmitted from one cat to another primarily through bite wounds, FIV is most common among cats that are exposed to the outdoors or live in multiple-cat households.

In 2002, a vaccine to protect against feline AIDS was approved for commercial production and veterinary use by the U.S.D.A., culminating 15 years of work starting with two UC Davis researchers, Janet Yamamoto and Niels Pedersen who co-discovered FIV. Their work led to a vaccine jointly patented at UC Davis and University of Florida, where Yamamoto is now a professor. Licensee Fort Dodge Animal Health, a division of Wyeth, now offers the vaccine to licensed veterinarians under the name Fel-O-Vax.

Double Transgenic Mouse for Alzheimer's — University of South Florida

Work by University of South Florida researchers, Dr. Karen Duff and Dr. John Hardy, led to a significant advance in the field of transgenic animal models of Alzheimer's Disease.

The double transgenic, presenilin (PS) and amyloid precursor protein (APP) mouse model takes significantly less time to demonstrate Alzheimer's pathology than previous models. The PS/APP mouse demonstrates progressive, age-related, impaired cognitive function that correlates with plaque deposition in the brain.

Widely non-exclusively licensed in fiscal year 2002, under U.S. Patent 5,989,094 and foreign equivalents, the mouse model is accepted by the academic research community as well as by pharmaceutical and biotechnology corporations. The PS/APP mouse provides an ideal model for research, including drug discovery for Alzheimer's, and realizes savings in time and therefore money.

Testing for and Treating Creatine Transporter Deficiency — University of Cincinnati and The Cincinnati Children's Research Foundation

In a far-reaching collaboration, researchers at The University of Cincinnati Medical Center and The Cincinnati Children's Research Foundation, have identified a new genetic disorder, Creatine Transporter Deficiency, and have identified the X chromosome linked defect that is responsible. The disorder presents a range of symptoms including speech and language impairment in children, potentially resulting in severe mental retardation. The lifetime care issues for sufferers are massive, measured not just in fiscal terms but also in the direct impact on carriers.

Under a licensing and funding arrangement agreed to in fiscal year 2002, the researchers will collaborate with The Avicena Group Inc., building on promising results to identify both a diagnostic and an effective therapy. Avicena is a Massachusetts and California based biotechnology company with a long-standing interest in the role of the creatine kinase system in central nervous system disorders.

The two Cincinnati institutions are pleased with this model of collaboration on joint research and licensing efforts with industry.

Electronics

Carnegie Mellon University Start-up Firm Akustica, Inc. Improves Cellular Voice Quality

In 2001, Carnegie Mellon University's MEMS Laboratory Director Kaigham ("Ken") Gabriel joined with James H. Rock to create Akustica, Inc., a start-up company. Starting in fiscal year 2002, the company has raised $12 million in venture funding to date.

The licensed technology relates to fabricating membranes using standard semiconductor processes. These membranes react to sound much like a traditional microphone with the voice creating variations in air pressure that hit the membrane, moving it. The membrane's motion is converted into a voltage. Each individual membrane can target specific audio frequencies with better sensitivity than existing electret condenser microphones.

Akustica created multi-membrane microphones with an on-chip analog amplifier that can more accurately capture desired sounds and reduce unwanted noise in mobile phones, hearing aids and other electronics devices. Akustica is working with a leading cell phone company to develop a microphone chip product for cell phone and hearing aid applications.

Getting a Better View with Advanced Display Technology — The University of Akron

New surface plate technology, developed at The University of Akron, promises to make viewing computer monitors and a wide variety of consumer products easier on your eyes was licensed in 2002 to Nitto Denko.

Invented by Drs. Frank Harris and Stephen Cheng of The University of Akron's Department of Polymer Science, the technology is a polymer film that improves the range of view for flat panel displays. Supported by NASA and the NSF, the technology was issued US Patent 5,580,950 in 1996, titled "Negative Birefringent Rigid Rod Polymer Films".

In May 2002, The University of Akron licensed the technology to Nitto Denko of Osaka, Japan, one of the world's leading producers of flat panel displays and created a research agreement for ongoing development. Nitto Denko has the largest worldwide market share for optical films for specialized industrial and medical applications and is incorporating the technology into the company's large display monitors.

Broadband Wiring in the Hospitality Industry — Virginia Tech

Turbowave licensed the Stub Loaded Helix Antenna technology from VTIP and deployed it in fiscal year 2002 as wireless high-speed or broadband Internet access in guest rooms, conference rooms and public areas in more than 100 U.S. hotels in the hospitality industry.

These smart antennas are designed to increase transmission range and reduce multipath interference created by reflections from objects along the path to an access point.

The technology is included in the Stub Loaded Helix Array which is designed to make long-range shots in remote areas and in a smaller end user antenna, which attaches to a wireless card and increases signal strength.

Software

Teoma Technology — Rutgers, The State University of New Jersey

Teoma Technology was a start-up company financed by computer technology entrepreneur Scott Baxter. Teoma licensed an innovative search engine developed in the Rutgers University Computer Science Department by Dr. Apostolos Gerasoulis in 1998. Teoma took the raw code from the lab, and developed it into a commercially usable code.

Teoma's search technology uses a unique approach for dividing the web into natural communities, page ranking and analyzing topic-specific web content and making it a more functional search engine than its competitors. It has been hailed as "the next best thing in search engines." Many in the industry now recognize Teoma as superior to Google.

Teoma was acquired by and combined with Ask Jeeves' interface in September 2001, increasing Ask Jeeves' number of searches by 25%. In fiscal year 2002, Teoma successfully moved into the market generating $22,316 in license income and in fiscal year 2003 Rutgers received $624,893 from license income and the sale of stock.

Sponsored Programs Database — Western Kentucky University

A unique administrative need at Western Kentucky University led to a fruitful collaboration between Regina Allen, Operations Specialist in the Office of Sponsored Programs, and Jeffrey Alan Jones, a Senior Programmer/Consultant in the Micro-computing Center.

Using commonly available commercial software, the creators devised a relational database, complete with a single form interface that is used to manipulate, manage and calculate proposal and award data. It is able to link and track data, calculate totals, generate reports and provide other information that is of interest to the manager.

Available non-exclusively to any academic, research or clinical facility that engages in sponsored programs administration, the product was born from necessity and cost nothing but the creators' ingenuity and effort. It was introduced to the market in the summer of 2002 strictly by word of mouth, and to date has netted more than $10,000 for WKU.

Environment

Generating Environmentally Friendly, Low-Cost Electricity — University of California, Irvine and University of Florida

UC Irvine and the University of Florida have jointly invented a plasma electric generator (PEG) that, once successfully demonstrated in the next several years, will produce clean, scalable, distributed electric power without the use of fossil fuels or radioactive waste problems. PEG uses a proton beam injected into a cycling, field-reversed boron-11 material where the reaction is contained by super-conducting magnets. The resulting plasma is channeled through a direct converter (reverse cyclotron process) to create direct electric power. Such electric power generation, operating with hydrogen and boron fuel, could produce environmentally friendly electricity at a fraction of the cost of current power plants.

Core technologies have been developed through cooperation agreements between UCI and the University of Florida, and a technology transfer agreement is in place with Tri Alpha Energy, a venture-backed start-up company near UCI. The company is also applying UCI technology to the economic and safe destruction of high-level waste from nuclear weapons development and spent fuel rods from nuclear fission plants.

2.0 The FY 2002 AUTM Licensing Survey

2.1 Data Collection

The survey population for fiscal year 2002 consisted of 364 institutions[ii], up from 335 in fiscal year 2001, and included 225 U.S. universities and colleges, 62 U.S. hospitals and research institutes, 74 Canadian institutions, and 3 third-party patent management and investment firms. The institutions surveyed were asked to provide a best estimate for each question if an exact response was not known. In a few instances, best estimates were provided, and, at times, responses were rounded to the nearest thousand or million. Data that were not available are noted as "N.A." Respondents were asked to submit data through a secure Web site. Data collection started on June 3, 2003 and was completed on September 8, 2003.

2.2 Respondents

Two hundred and twenty two organizations, 61.0% of those contacted, responded, an increase of 24 or 12.1% from fiscal year 2001. The respondents included:

- 156 U.S. universities, a response rate of 69.3% and an increase of 14 from 142 in fiscal year 2001;
- 32 U.S. hospitals and research institutes, a response rate of 51.6% and an increase of 4 from 28 in fiscal year 2001;
- 33 Canadian institutions, a response rate of 44.6% and an increase of 6 from 27 in fiscal year 2001; and
- 1 third-party patent management and investment firm, a response rate of 33.3% and the same as in fiscal year 2001.

The increase of 24 resulted from 183 of the 198 respondents to the fiscal year 2001 Survey responding to the fiscal year 2002 Survey and 39 institutions that had not responded to the fiscal year 2001 Survey responding to the fiscal year 2002 Survey. Fifteen of the institutions that responded to the fiscal year 2001 Survey did not respond to the fiscal year 2002 Survey. Because of the significant turnover in Survey respondents and the substantial increase in the number of respondents, several of whom were major institutions whose figures have a significant impact on the totals, year-to-year changes in the individual metrics are divided into the changes reported by those institutions that responded in both fiscal year 2001 and fiscal year 2002 (referred to in the text as the "recurrent respon-

ders") and the net change between the responses of the 39 new fiscal year 2002 respondents and the 15 who responded in fiscal year 2001 but did not respond in fiscal year 2002 (referred to in the text as the "net new responders"). The one-year recurrent change gives a more accurate picture of current trends than does the total year-to-year change.

Follow-up efforts were heavily concentrated toward the top 100 universities selected according to research expenditures and identified in the National Science Foundation's (NSF) report entitled Federal Science and Engineering Support to Universities, Colleges, and Nonprofit Institutions (fiscal year 2001)[iii]. This effort resulted in a 92% response rate from these top institutions. It should be noted that the NSF Leading 100 Research Institutions includes several individual campuses of state university systems (specifically, 7 campuses of the University of California System and 2 of the University of Illinois System) that report to the AUTM Survey as part of a single university-wide report. It should be further noted that certain other multi-campus state university systems (specifically, the University of Arkansas System, the University of Maryland System, the University of North Carolina System, the University of Texas System and the University of Wisconsin System) chose to report to the AUTM Survey on an individual campus basis.

Nine institutions — five U.S. Universities, two U.S. Hospitals and Research Institutes and two Canadian institutions — requested that their names be withheld. Their responses are included in the totals for the various categories of institutions but are omitted from the listings of data for individual institutions.

Summaries of the response rate and of the number of responses by the various types of respondent to the Survey in fiscal year 2002 and in previous years are shown in Tables S-1 and S-2. Table S-1 highlights the participation of the major research institutions. Table S-2 shows the number of responses by type of respondent.

Table S-1: Overall Response Rate to the Survey and Participation of Major Research Universities 1992 to FY 2002

	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
# Surveyed	260	250	255	279	300	307	312	322	332	335	364
Overall Response Rate	50%	63%	62%	62%	58%	57%	57%	59%	57%	59%	60%
Top 100 Research Universitites	66%	85%	84%	87%	89%	90%	92%	94%	94%	92%	94%*

** Based on 2001 NSF Listing*

Table S-2: Survey Respondent Information

Fiscal Year	Surveyed	Responses				
	Population	U.S. Universities	U.S. Hospitals & Research Institutes	Canadian Institutions	Patent Management Firms	Total
FY 1991 and 1992	260	98	20	10	2	130
FY 1993	250	117	26	12	3	158
FY 1994	255	120	24	12	3	159
FY 1995	279	127	27	16	3	173
FY 1996	300	131	26	14	2	173
FY 1997	307	132	26	16	1	175
FY 1998	312	132	26	20	1	179
FY 1999	322	139	29	20	2	190
FY 2000	332	142	25	22	1	190
FY 2001	335	142	28	27	1	198
FY 2002	364	156	32	33	1	222
Responded 2001-2002		130	26	26	1	183
Responded 1991-2002		57	11	6	1	75

3.0 Summary of Results

This Summary follows the technology transfer process: resources devoted to technology transfer, research support, invention disclosures, patent applications, issued patents, licensing information and start-up companies. The definitions of the terms used in the Survey are in Attachment C. Defined terms are shown capitalized.

3.1 Resources

3.1.A Maturity of Technology Transfer Program

Institutions have started their technology transfer programs at different times. The age of a program is a significant factor in comparing performance because of the time needed to develop a portfolio of intellectual property to license, to build up a body of expertise, a culture of technology transfer within the institution and the time needed for licensees to develop and market products. While a few institutions had established their programs before the passage of the Bayh-Dole Act in 1980, the pace of establishment accelerated after Bayh-Dole. Figures 1 and 2 show the Program Start Date (the year when the institution first devoted one half of an FTE to technology transfer) of U.S. universities and U.S. hospitals and research institutes respectively.

Figure 1: Technology Transfer Program Start Date of U.S. Universities

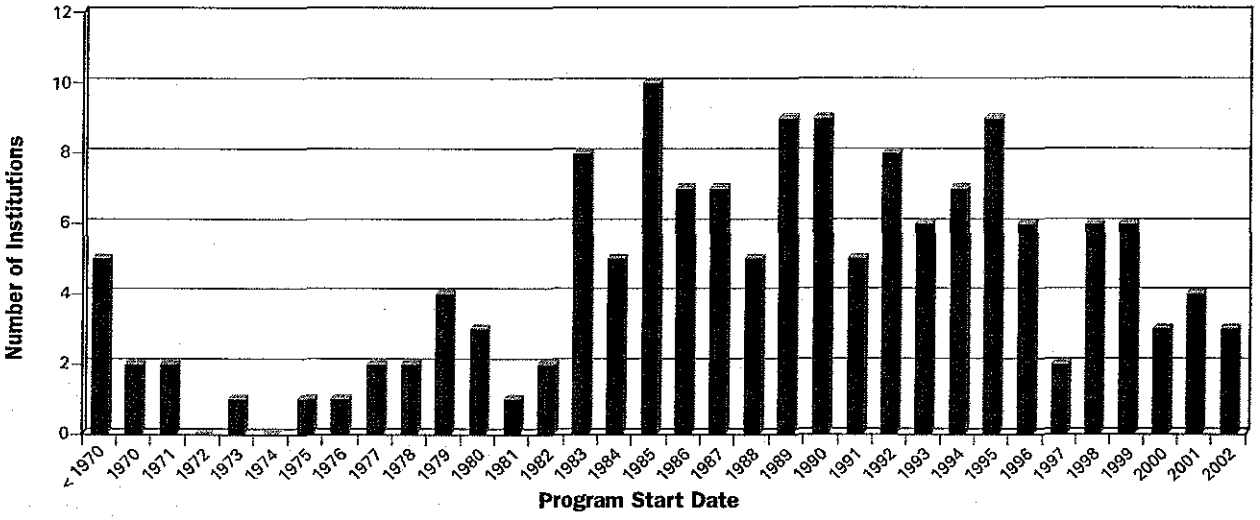
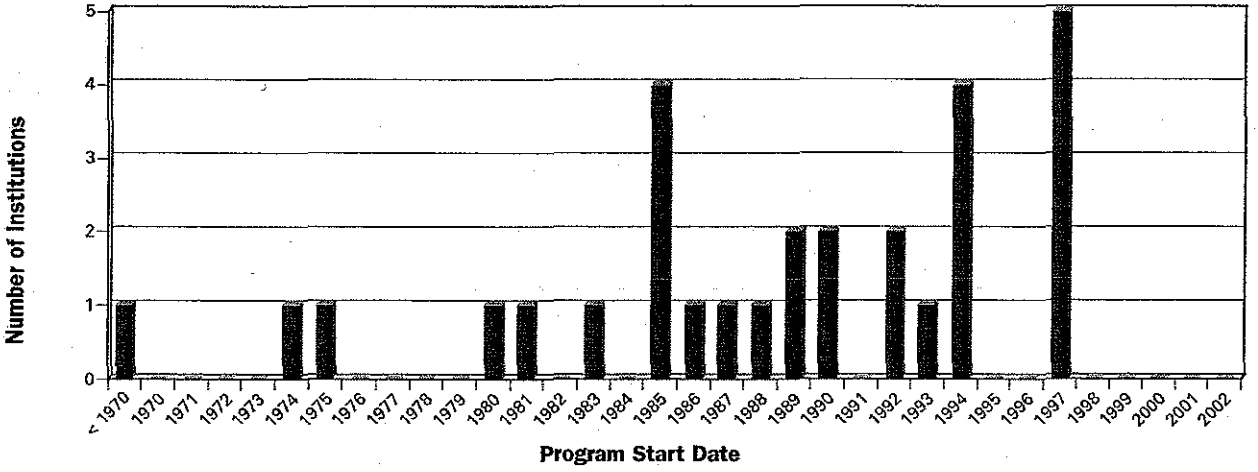


Figure 2: Technology Transfer Program Start Date of U.S. Hospitals and Research Institutes



3.1.B Staffing

Two hundred and fifteen respondents reported a total of 846 Licensing FTE's, an average of just fewer than four FTE's per office. This figure was up by 17.9% or 128 over fiscal year 2001 levels, of which 89 were reported by recurrent respondents and 39 were from the net new responders. Two hundred and sixteen institutions reported that they had a total of 840 Other FTE's (i.e., administrative support staff), also an average of just fewer than four per office. These figures were up 15.8% or 114 more than fiscal year 2001 levels, of which 81 were reported by recurrent respondents and 33 were from the net new responders. There is a considerable range of size of offices. Figures 3 and 4 show the staffing levels of responding U.S. universities and U.S. hospitals and research institutes respectively. Table S-3 shows how staffing levels have increased since 1992.

3.2 Research Support

Two hundred and twelve institutions reported Total Research Expenditures of $37.018 billion, an increase of $5.258 billion or 16.6% from the $31.760 billion reported in fiscal year 2001, of which $3.242

Figure 4: Technology Transfer Office Staffing Levels, U.S. Hospitals and Research Institutes, 2002

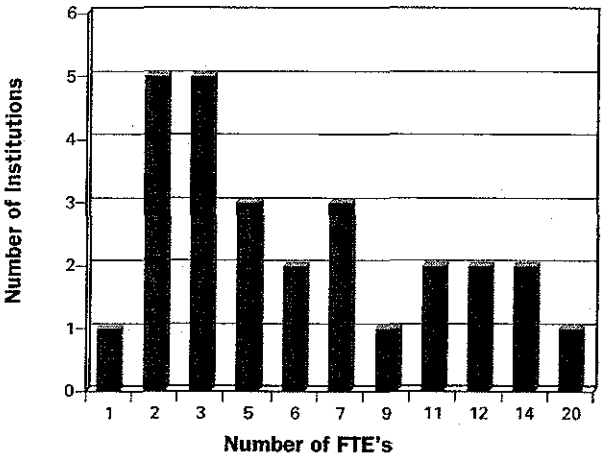


Figure 3: Technology Transfer Office Staffing Levels, U.S. Universities, 2002

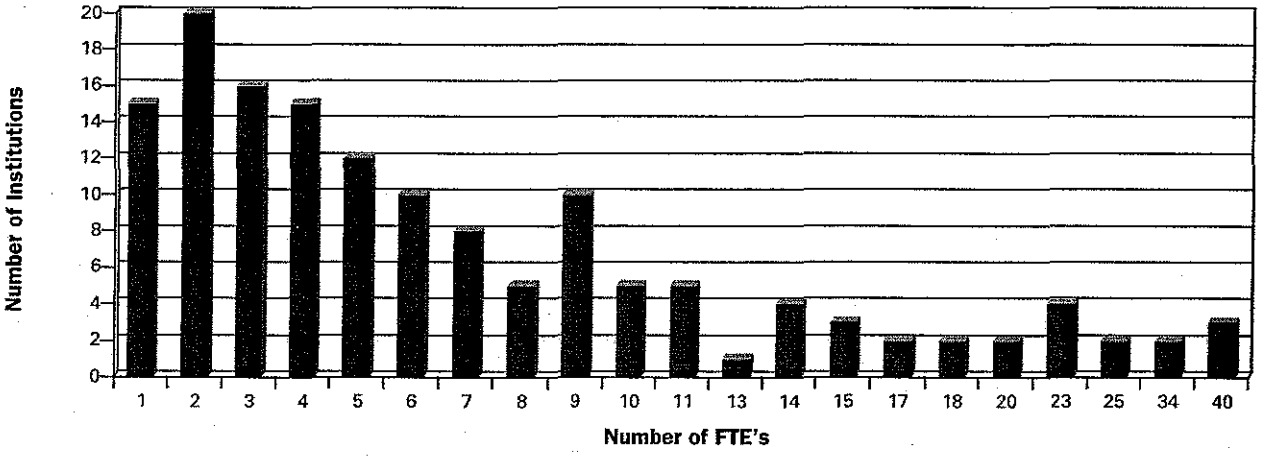


Table S-3: Historic Staffing Levels of Technology Transfer Offices

	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
Licensing FTEs	254.8	330.1	338.3	349.9	N.A.*	477.4	522.6	556.0	633.8	717.9	846.2
Other FTEs	182.8	226.9	229.0	226.2	N.A.*	509.4	540.5	598.1	668.6	725.7	840.0
Total FTEs	437.6	557.0	567.3	576.1	N.A.*	986.9	1,063.1	1,154.0	1,302.4	1,443.6	1,686.1

** The FTE Question asked in the FY 1996 Survey was not consistent with the question asked in subsequent years. For FY 1992 – 1995, two questions were asked, one of which was consistent with the 1997 and subsequent questions.*

billion was reported by recurrent respondents and $2.015 billion was from the net new responders. $23.118 billion or 62.5% was funded by federal government sources, an increase of $3.178 billion or 15.8% more than fiscal year 2001, of which $2.019 billion was reported by recurrent respondents and $1.158 billion was reported by the net new responders. $2.974 billion or 8.0% was funded by industrial sources, an increase of $190.3 million or 6.8% from fiscal year 2001, of which a decrease of $27.8 million was reported by recurrent respondents while an increase of $218.1 million was reported by the net new responders. The balance comes from state and local government sources, foundations, individuals and the institution itself.

Table S-4 shows Total Research Expenditures of U.S. universities, hospitals and nonprofit research institutes that identified the federal and industrial

Figure 6: Distribution of Size of Research Programs of U.S. Universities, 2002

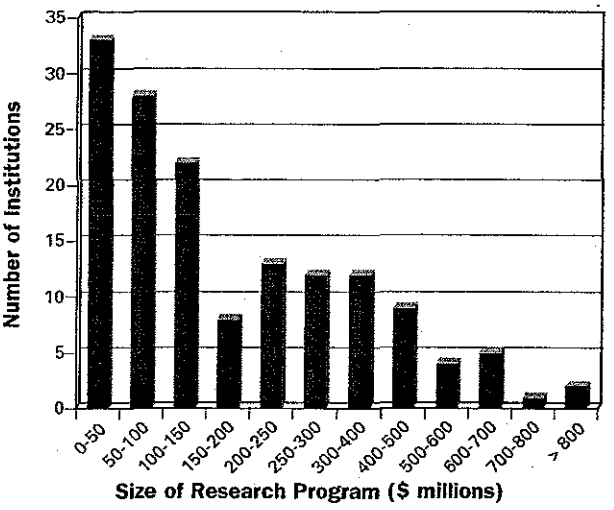


Figure 5: Research Expenditures for U.S. Universities, Hospitals and Research Institutes, 1991 – 2002

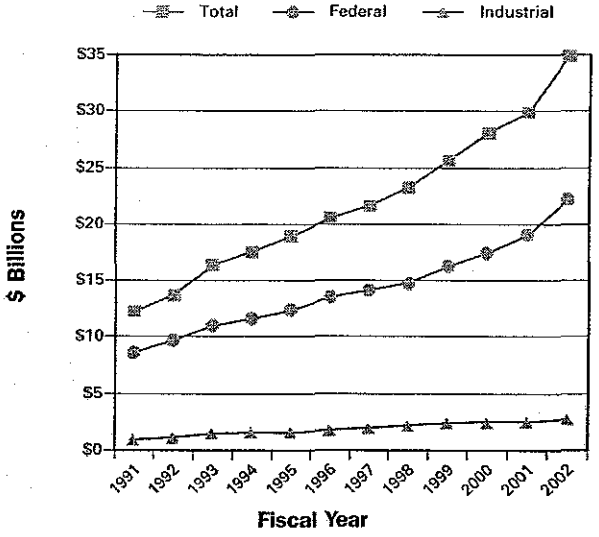


Figure 7: Distribution of Size of Research Programs of U.S. Hospitals and Research Institutes, 2002

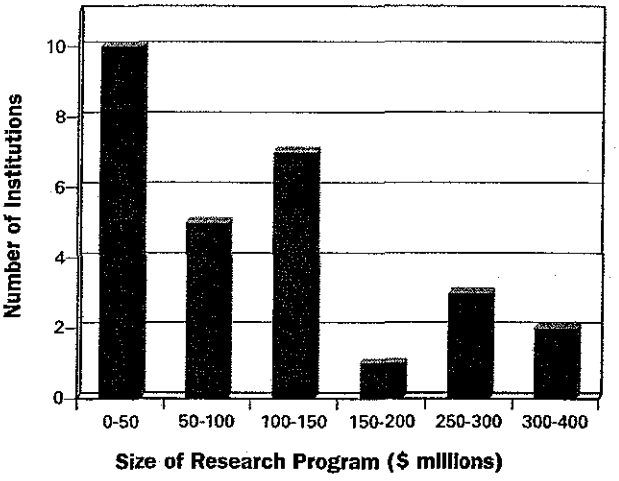


Table S-4: Amount of Total Research Support From Federal and Industrial Sources for U.S. Universities, Hospitals and Research Institutes, 1991 – 2002

	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
Total Research Expenditures ($ Billions)	12.8	14.2	17.1	18.2	19.9	21.4	22.7	24.4	26.8	29.5	31.8	37.0
% Federal	69%	69%	67%	66%	67%	67%	68%	65%	65%	65%	67%	62%
% Industrial	7%	8%	8%	8%	8%	9%	9%	9%	9%	9%	8%	8%

fraction of such expenditures over the twelve-year period during which this survey has been conducted. Sixty-two to sixty-nine percent (62-69%) of the research expenditures were from federal sources, and 7-9% were from industrial sources. This data is presented graphically in Figure 5. The federal government has substantially increased its funding of academic research over the time period. The National Institutes of Health budget was doubled over the past five years and the National Science Foundation budget is at the start of a similar five-year program in which it will double. Figures 6 and 7 show the distribution of sizes of the research programs of U.S. universities and U.S. hospitals and research institutes, respectively.

3.3 Invention Disclosures and Patents

3.3.A Invention Disclosures

In fiscal year 2002, 15,573 Invention Disclosures were received by 221 institutions, an increase of 2,004 or 14.8% from the 13,569 disclosures received by 196 institutions in fiscal year 2001, of which an additional 1,041 was reported by recurrent respondents and an additional 963 was reported by the net new responders. Table S-5 reports Invention Disclosures received for all respondents since 1991. Figures 8 and 9 show the distribution of the numbers of Invention Disclosures received by U.S. universities and U.S. hospitals and research institutes, respectively.

3.3.B Patents

New U.S. Patent Applications Filed by 216 institutions rose 13.6% or 929 in fiscal year 2002 to 7,741, an increase from 6,812 filed by 195 institutions in fiscal year 2001, of which an additional 651 was reported by recurrent respondents and an additional 278 was reported by the net new responders. New U.S. Patent Applications Filed since 1991 are shown in Table S-6. Figures 10 and 11 show the distribution of the numbers of New U.S. Patent Applications Filed by U.S. universities and U.S. hospitals and research institutes respectively.

The filing of a New U.S. Patent Application most frequently corresponds to a decision to seek patent protection on a single Invention Disclosure, though

Figure 8: Invention Disclosures Received by U.S. Universities, 2002

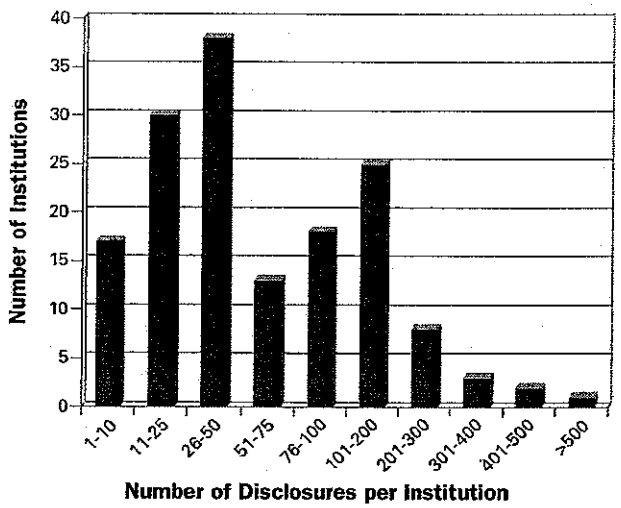


Figure 9: Invention Disclosures Received by U.S. Hospitals and Research Institutes, 2002

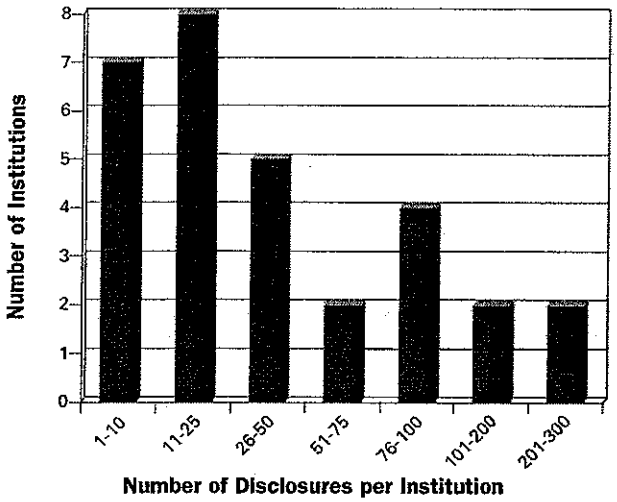


Table S-5: Invention Disclosures Received 1991 – 2002, by All Respondents

	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
Number of Respondents	130	130	158	159	173	173	175	179	190	190	196	222
Invention Disclosures Received	6,337	7,345	8,581	8,743	9,789	10,178	11,303	11,784	12,324	13,032	13,569	15,573

sometimes two or more invention disclosures are combined into a single patent application, and, conversely, a single disclosure can occasionally generate more than one new patent filing. Equally, time sometimes elapses between receipt of an Invention Disclosure and the filing of a New U.S. Patent Application, so that the decision whether to seek protection on an Invention Disclosure may not be made in the same year that the Invention Disclosure was received. With these caveats in mind, the ratio of New U.S. Patent Applications Filed to Invention Disclosures received has increased as technology transfer programs have matured. Figure 12 illustrates this increase, from 25.9% in fiscal year 1991 to 47.4% in fiscal year 2002, which was down slightly from 50.2% in fiscal year 2001.

Two hundred nineteen institutions reported that Total U.S. Patent Applications Filed[iv] rose in fiscal year 2002 to 12,929, an increase of 1,664 or 14.8% more than the 11,265 filed by 195 institutions in fiscal year 2001, of which an additional 858 was reported by recurrent respondents and an additional 806 was reported by the net new responders (See Table S-6). The number of Total U.S. Patent Applications Filed is greater than the number of New U.S. Patent Applications Filed because of procedures at the U.S. Patent Office that allow applicants to re-file a patent application after two rejections of the application by the Patent Office, or because the Patent Office determines that there are multiple inventions in a single new patent application, necessitating the filing of "divisional" applications. Since many patent applications are considered more than twice before being allowed, a single invention is frequently associated, procedurally, with more than one U.S. patent application. Figure 13 shows that offices manage approximately three U.S. patent prosecutions for every two new patent applica-

Figure 10: New U.S. Patent Applications Filed by U.S. Universities, 2002

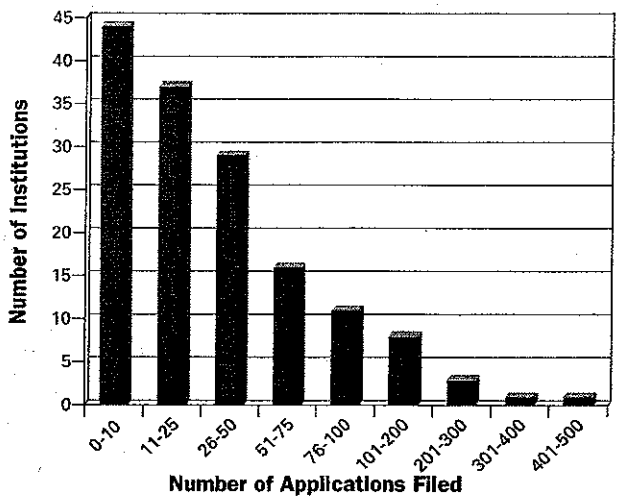


Figure 11: New U.S. Patent Applications Filed by U.S. Hospitals and Research Institutes, 2002

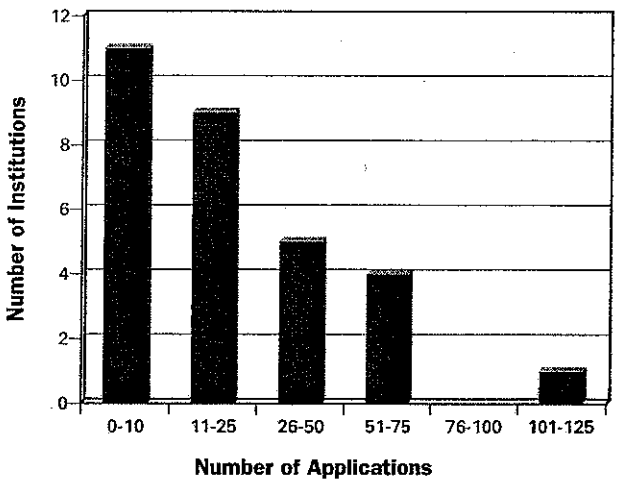


Table S-6: U.S. Patent Filings and Issuances by All Respondents FY 1991 – 2002

	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
Number of Respondents	130	130	158	159	173	173	175	179	190	190	195	219
New U.S. Patent Applications Filed	1,643	1,951	2,433	2,429	2,872	3,261	4,267	4,808	5,545	6,375	6,812	7,741
Total Patent Applications Filed	2,469	2,968	3,835	4,320	6,473	4,733	6,629	7,714	8,802	9,925	11,265	12,929
U.S. Patents Issued			1,603	1,874	1,833	2,095	2,645	3,224	3,661	3,764	3,721	3,673

tions filed. The fiscal year 1995 fluctuation in Total U.S. Patent Applications Filed is discussed in Footnote v.

Two hundred nineteen respondents reported that they received 3,673 U.S. Patents Issued[vi] in fiscal year 2002, a decrease of 48 or 1.3% relative to fiscal year 2001, which itself was down from fiscal year 2000. However, recurrent responders showed a decrease of 260, or 7.7%, while net new responders showed an increase of 212. Table S-6 shows U.S. Patents Issued for all respondents since fiscal year 1993 and Figure 14 shows U.S. Patents Issued as a percentage of both New U.S. Patent Applications Filed and Total U.S. Patent Applications Filed since 1993. It appears that the number of U.S. Patents Issued is not going up as rapidly as the rate at which patent applications are being filed. The 3,673 U.S. Patents Issued represented 2.0% of all utility patents granted by the U.S. Patent and Trademark Office in fiscal year 2002, down from 2.3% in fiscal year 2001. Figures 15 and 16 show the distribution of the numbers of New U.S. Patent Applications Filed by U.S. universities and U.S. hospitals and research institutes, respectively.

Legal Fees Expenditures[vii] were $194.8 million in fiscal year 2002 reported by 214 institutions, an increase of $33.7 million or 20.9% more than the $161.1 million reported in fiscal year 2001, of which an additional $25.6 million was reported by recurrent respondents and an additional $8.2 million was reported

Figure 12: New Patent Filings and Invention Disclosures Received, All Respondents, 1991 – 2002

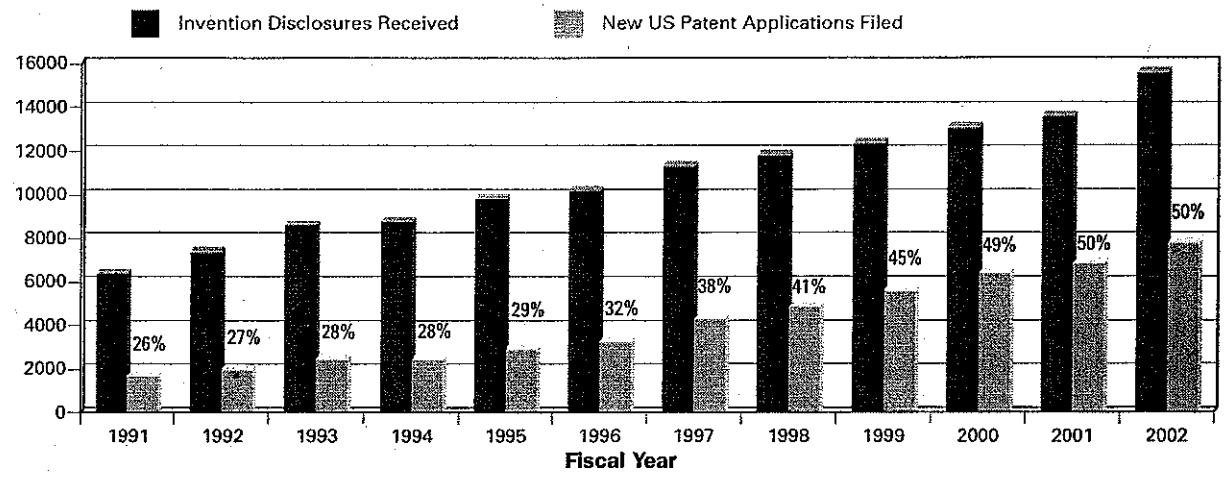
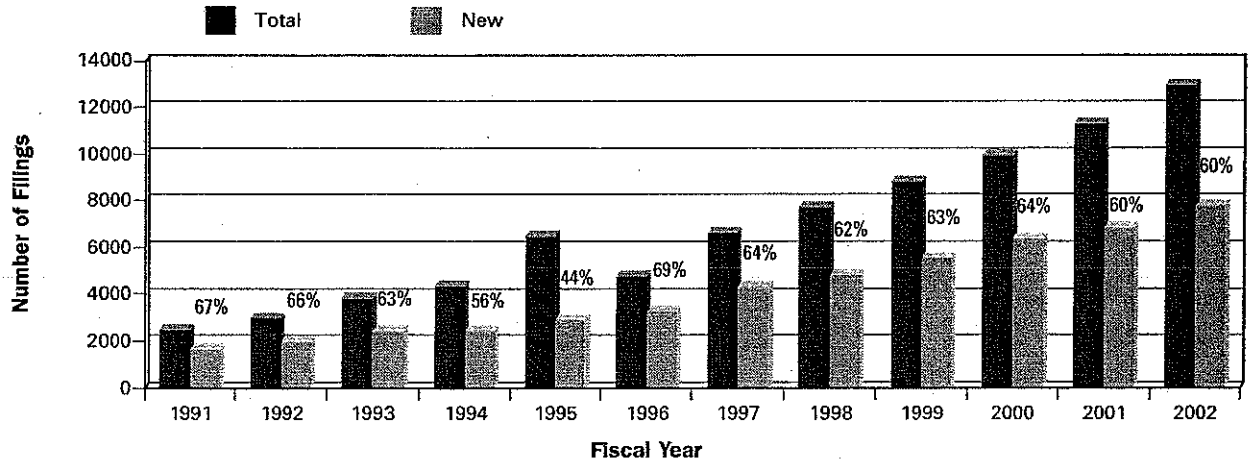


Figure 13: New U.S. Patent Filings and Total U.S. Patent Filings, All Respondents, 1991 – 2002



by net new responders. These costs are partially offset by licensees through Legal Fees Reimbursements. In fiscal year 2002, 207 institutions reported reimbursements of $82.7 million, 42.6% of Legal Fees Expenditures and an increase of $12.8 million or 18.4% more than the $69.9 million reported in fiscal year 2001, of which an additional $9.1 million was reported by recurrent respondents and an additional $3.7 million was reported by net new responders. The reimbursement rate in fiscal year 2001 was 43.5%. The definitions for Legal Fees Expenditures and Legal Fees Reimbursed have been changed over time to aid better reporting and analysis of these costs. Specifically, in fiscal year 1999, the definition for Legal Fees Expenditures was modified to explicitly omit major litigation expenses, so that the figures more accurately track patent prosecution costs.

Table S-7 shows Legal Fees Expenditures, Legal Fees Reimbursed and the percentage of Legal Fee Expenditures that were reimbursed since 1991. These figures are shown in Figure 17, which shows that the percentage of costs that is reimbursed has ranged between 30% and 48% and most recently has been around 43%, though the magnitude of non-reimbursed costs has increased about 250% during the past twelve years. Figures 18 and 19 show the distribution of Legal Fee Expenditures for U.S. universities and U.S. hospitals and research institutes, respectively.

3.4 Licensing

3.4.A Transactions

Two hundred nineteen respondents reported 4,673 Licenses and Options Executed in fiscal year 2002 up 615 or 15.2% more than fiscal year 2001, of which an additional 281 was reported by recurrent respondents and an additional 334 was reported by net new responders. The fiscal year 2001 total was down 7% from fiscal year 2000, the first decrease in transactions since the Survey started, and it is encouraging that both total transactions and transactions reported by recurrent respondents have turned back up. The 4,673 Licenses and Options Executed in fiscal year 2002 exceeded the

Figure 14: U.S. Patent Applications Issued as a Percentage of Total U.S. Patent Applications Filed and New U.S. Patent Applications Filed, 1993 – 2002

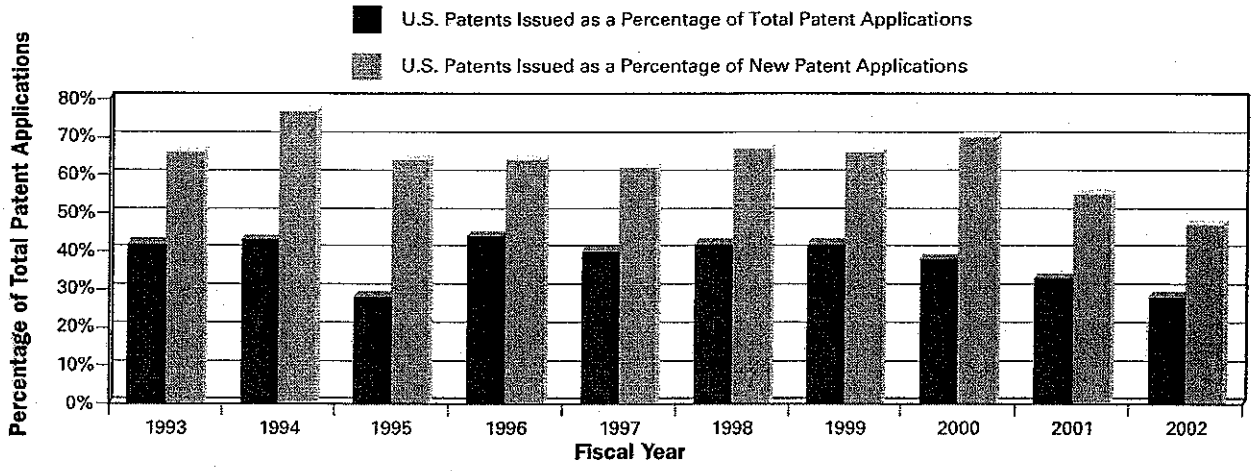


Table S-7: Legal Fees Expended and Reimbursed for All Respondents FY 1991 – 2002

	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
Number of Respondents	130	130	158	159	173	173	175	179	190	190	198	214
Legal Fees Expended ($ million)	$37	$46	$66	$69	$79	$93	$111	$122	$121	$142	$161	$195
Legal Fees Reimbursed ($ million)	$11	$16	$28	$33	$34	$37	$45	$51	$52	$64	$70	$83
% Reimbursed	29.7%	34.8%	42.4%	47.8%	43.0%	39.8%	40.5%	41.8%	43.0%	45.1%	43.5%	42.6%

4,362 executed in fiscal year 2000. The cumulative total of Licenses and Options Executed since fiscal year 1991 is 37,090 as shown in Table S-8. Figures 20 and 21 show the distribution in the number of Licenses/Options Executed for U.S. universities and U.S. hospitals and research institutes, respectively.

Of these Licenses and Options Executed since 1991, 217 institutions reported that 26,086 or 70.3% of the 37,090 cumulative total of Licenses and Options Executed since fiscal year 1991 were Active Licenses/Options in fiscal year 2002, an increase of 3,149 or 13.0% more than the total in fiscal year 2001, of which an additional 2,108 was reported by recurrent respondents and an additional 1,041 was reported by net new responders. The percentage of the cumulative total of Licenses and Options Executed that were Active Licenses/Options decreased marginally from 70.5% in fiscal year 2001 to 70.3% in fiscal year 2002. Figures 22 and 23 show the distribution in the number of Active Licenses/Options at the end of fiscal year 2002 for U.S. universities and U.S. hospitals and research institutes, respectively.

Figure 15: U.S. Patents Issued to U.S. Universities, 2002

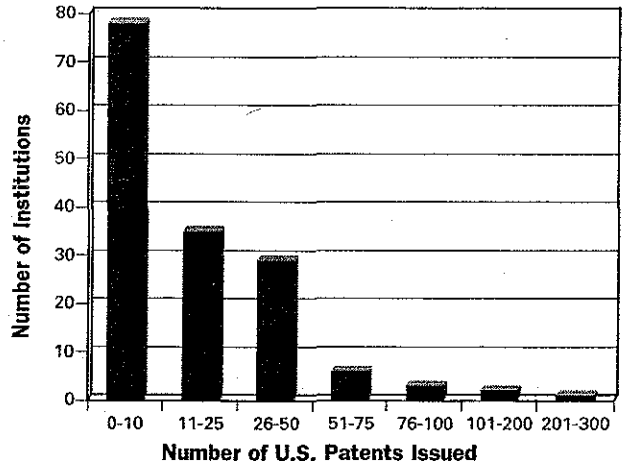


Figure 16: U.S. Patents Issued to U.S. Hospitals and Research Institutes, 2002

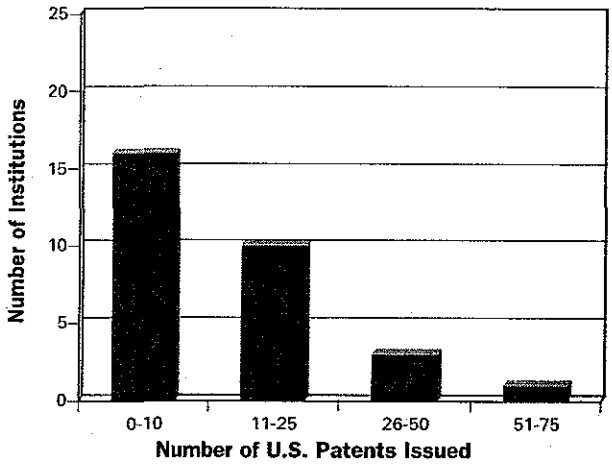
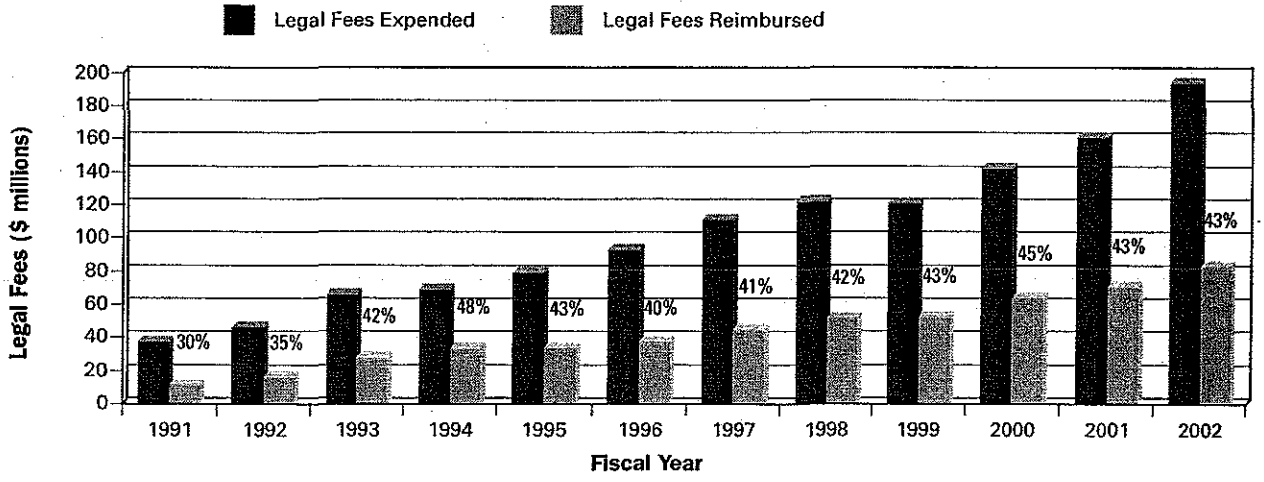


Figure 17: U.S. Patents Issued to U.S. Hospitals and Research Institutes, 2002



3.4.B Size of Licensee Company

Information was provided on the type of companies with which licenses and options were executed. Respondents were asked to classify the type of company with which licenses and options were executed into Start-Up Company, Small Company and Large Company. As shown in Table S-10, company information was provided for 4,548 of all Licenses and Options Executed, which was 97.3% of the 4,673 Licenses and Options Executed. Fourteen point six percent (14.6%) of the licenses were with Start-Up Companies (i.e., companies established specifically to develop the licensed technology) down from 16.5% in fiscal year 2001. Fifty-four point one percent (54.1%) of the Licenses and Options Executed were with existing Small Companies (companies employing fewer than 500 people), up from 50.1% in fiscal year 2001. Thirty-one point eight percent of the Licenses and Options Executed were with Large Companies (com-

Figure 19: Legal Fees Expended by U.S. Hospitals and Research Institutes, 2002

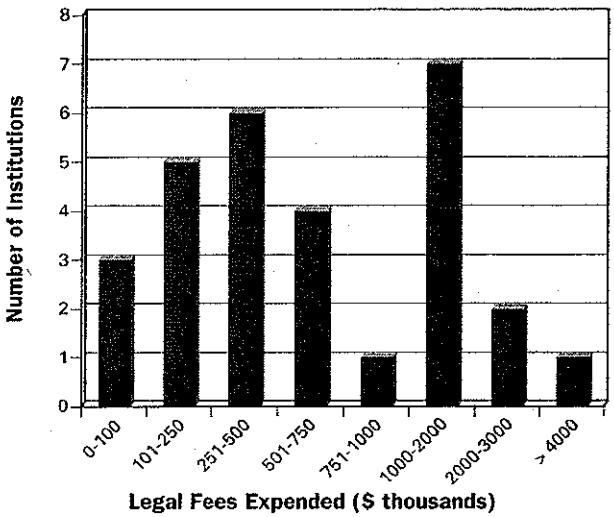


Figure 18: Legal Fees Expended by U.S. to U.S. Universities, 2002

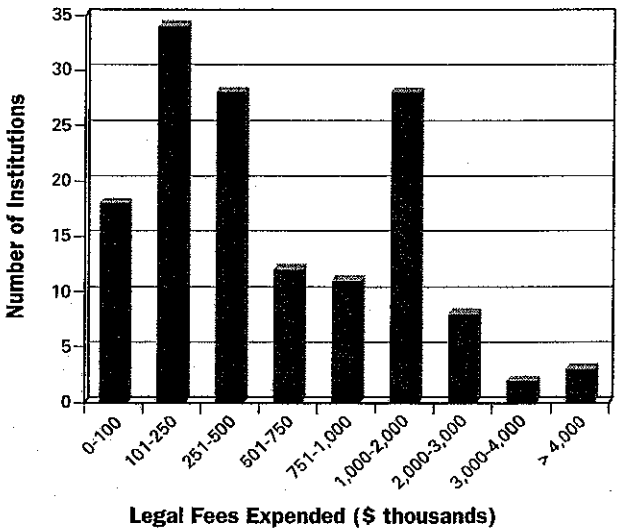


Figure 20: Licenses/Options Executed by U.S. Universities, 2002

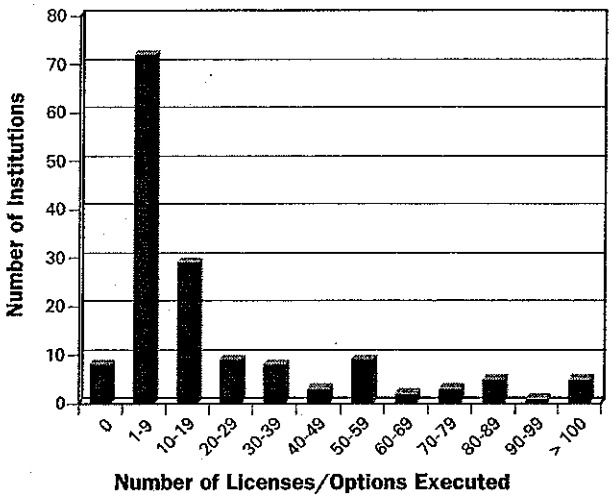
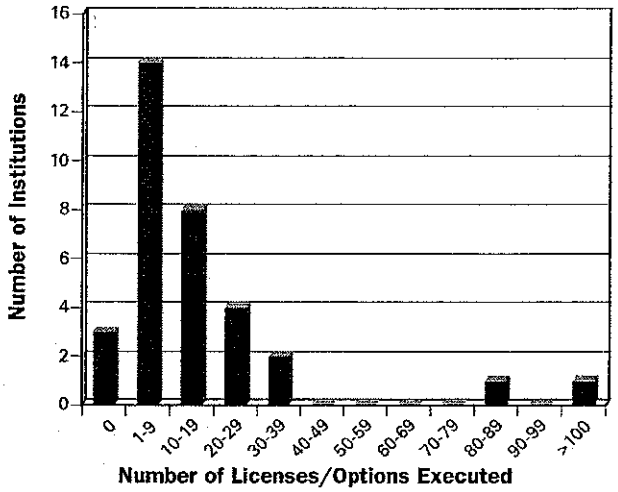


Table S-8: Licenses and Options Executed and Active, 1991 – 2002

	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
Number of Respondents	130	130	158	159	173	173	175	179	190	190	197	219
Licenses and Options Executed	1,278	1,741	2,227	2,484	2,616	2,741	3,328	3,668	3,914	4,362	4,058	4,673
Number of Respondents		125	151	153	170	170	170	169	185	186	192	217
Cumulative Active Licenses		7,209	8,805	9,943	11,806	12,951	15,328	17,088	18,617	20,968	22,937	26,086

Figure 21: Licenses/Options Executed by U.S. Hospitals and Research Institutes, 2002



panies employing more than 500 people), down from 33.4% in fiscal year 2001.

The Bayh-Dole Act requires licensors of inventions made with U.S. federal funding to show a preference for licensing these inventions to small companies. Sixty-eight point two percent (68.2%) of licenses granted by U.S. universities, U.S. hospitals and research institutes were to Start-Up and Small Companies combined, while 31.8% were to Large Companies, as compared with 66.6% and 33.4% respectively in fiscal year 2001. This requirement of the Bayh-Dole Act is clearly being met.

3.4.C Exclusivity

Two hundred fourteen respondents reported on the exclusivity of 4,594 or 98.3% of the Licenses and Options Executed. (See Table S-9.) Of the total, 46.5% were Exclusive Licenses, down from 48.0% in fiscal year 2001. The balance, 53.5%, was Nonexclusive Licenses.

Figure 22: Cumulative Active License/Options with U.S. Universities, 2002

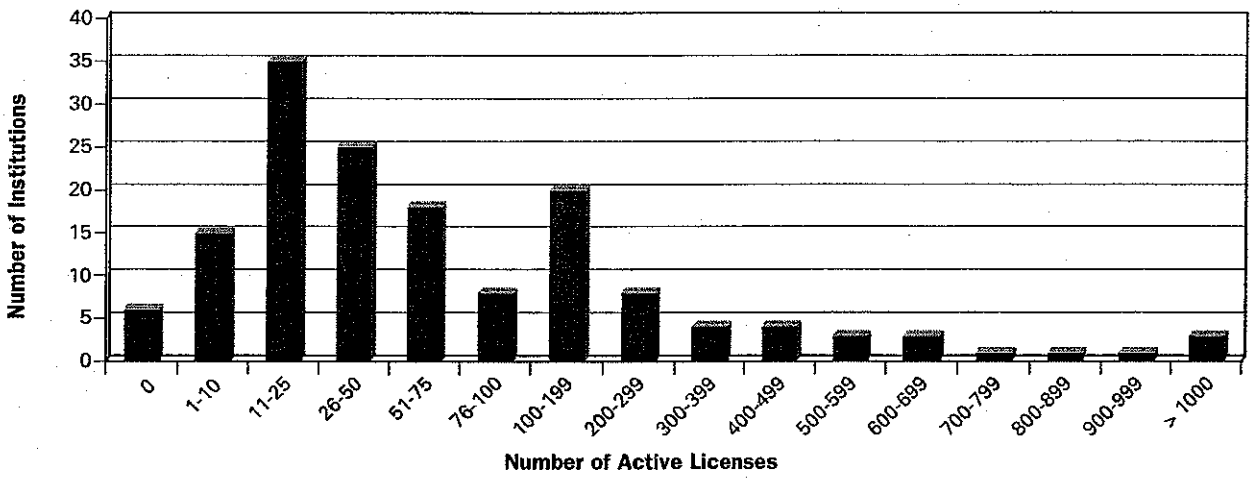


Table S-9: Licenses and Options Executed in 2002: Exclusive vs. Non-Exclusive

		Licenses and Options Executed				
FY 2002	Number of Respondents	Total	Exclusive	% of Total	Non Exclusive	% of Total
U.S. Universities	151	3,660	1,711	47%	1,949	53%
U.S. Hospitals & Research Institutes	30	507	231	46%	276	54%
Canadian Institutions	32	362	195	54%	167	46%
Patent Management and Investment Firms	1	65	–	0%	65	100%
All Respondents	214	4,594	2,137	47%	2,457	53%

Participants were asked to further report on the exclusivity of the licenses granted to the three categories of companies that the Survey distinguishes — Start-Up Companies, Small Companies and Large Companies. Information was provided for 4,509, 96.5% of the total Licenses and Options Executed. The results are presented in Table S-11 and illustrated in Figure 24. Ninety-one percent (91.0%) of the Licenses/Options Executed with Start-Up Companies were Exclusive Licenses, compared with 90.8% in fiscal year 2001; 45.4% of the Licenses/Options Executed with Small Companies were Exclusive Licenses, compared with 47.1% in fiscal year 2001; and 38.7% of the Licenses/Options Executed with Large Companies were Exclusive Licenses, compared with 32.9% in fiscal year 2001.

Figure 24 illustrates the percent of licenses that are exclusive by company type for fiscal year 2002. The Survey has collected these data since fiscal year 1998. The proportion of Exclusive Licenses granted to Start-Up Companies and Small Companies has been essentially stable.

Figure 23: Active License/Options with U.S. Hospitals and Research Institutes, 2002

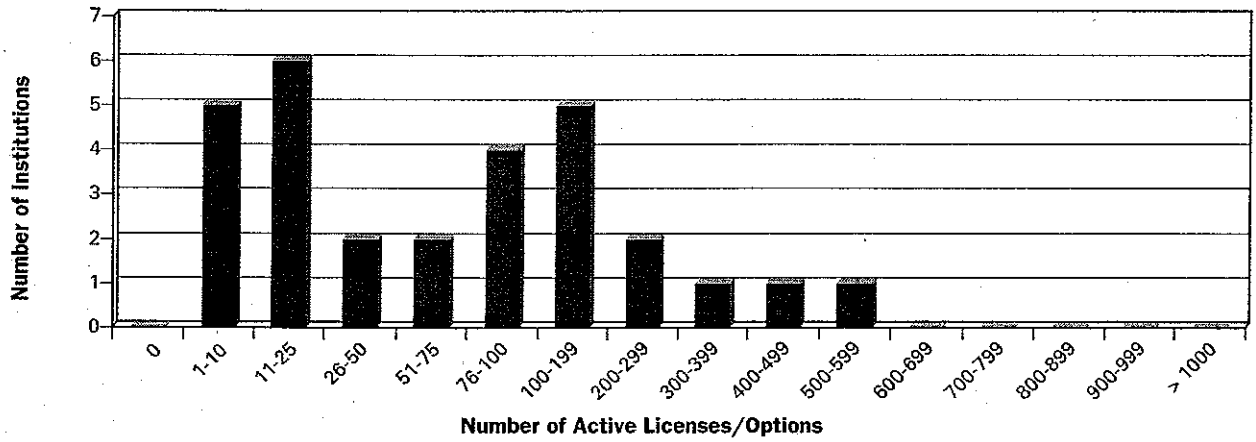


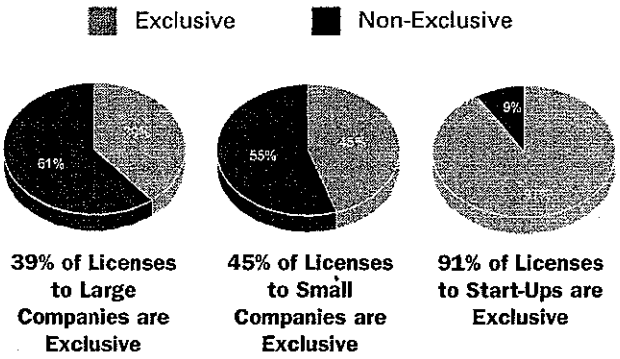
Table S-10: Licenses and Options Executed in 2002: Type of Licensee Company

		Licenses and Options Executed						
FY 2002	Number of Respondents	Total	Start-Up Companies	% of Total	Small Companies	% of Total	Large Companies	% of Total
U.S. Universities	150	3,567	542	15%	1,987	56%	1,038	29%
U.S. Hospitals & Research Institutes	29	504	51	10%	243	48%	210	42%
Canadian Institutions	31	349	49	14%	140	40%	160	46%
Patent Management Firms	1	65	0	0%	30	46%	35	54%
All Respondents	211	4,485	642	14%	2,400	54%	1,443	32%

Table S-11: Exclusivity of Licenses and Options Executed in 2002 by Type of Licensee Company

		Licenses and Options Executed						
			Start-Up		Small		Large	
FY 2002	Respondents	Total	Exclusive	Non-Exclusive	Exclusive	Non-Exclusive	Exclusive	Non-Exclusive
U.S. Universities	150	3,579	491	51	890	1,109	442	596
U.S. Hospitals & Research Institutes	29	504	45	6	127	116	70	140
Canadian Institutions	31	349	48	1	78	62	47	113
Patent Management Firms	1	65	–	–	–	30	–	35
All Respondents	211	4,497	584	58	1,095	1,317	559	884

Figure 24: Exclusivity Patterns Within Company Types, All Respondents, 2002



The percent of Licenses/Options to Large Companies that were exclusive trended steadily down from fiscal year 1998 through fiscal year 2001 before turning back up again in fiscal year 2002

3.4.D License Income Patterns

Two hundred eighteen institutions reported 10,866 Licenses/Options Yielding Income in fiscal year 2002, an increase of 1,159 or 11.9% more than the 9,707 reported in fiscal year 2001, of which an additional 604 was reported by recurrent respondents and an additional 555 was reported by net new responders. In other words, 41.7% of Active Licenses/Options yielded some type of License Income Received, compared with 42.3% in fiscal year 2001. The historical trend in Licenses/Options Yielding Income is shown in Table S-12.

Total License Income Received[viii, ix] in fiscal year 2002 reported by 219 institutions was $1.337 billion, an increase of $183.3 million or 15.9% from fiscal year 2001, of which an additional $93.4 million was reported by recurrent respondents and an additional $89.9 million was reported by net new responders. Because of the inter-institutional collaborations characteristic of science, two or more institutions frequently jointly own intellectual property. These institutions will generally agree to manage the intellectual property jointly, with one institution designated as the lead institution and thus having the responsibility to license the intellectual property, collect the royalties and distribute agreed upon shares to the other co-owner(s). To avoid double counting of the amounts paid to co-owners, respondents are asked to report the License Income Paid to Other Institutions. In fiscal year 2002, License Income Paid to Other Institutions was $69.9 million reported by 207 institutions, down $12.5 million or 15.1% from the $82.4 million reported by 185 institutions in fiscal year 2001. Recurrent respondents reported a decrease of $12.9 million while net new responders reported an additional $0.4 million.

Therefore Net License Income Received in fiscal year 2002 was $1.267 billion, an increase of $195.8 million or 18.3% more than $1.071 billion reported in fiscal year 2001. Figures 25 and 26 show the distribution in Total License Income Received by U.S. universities and U.S. hospitals and research institutes, respectively.

The Survey distinguishes between three sources of License Income: Running Royalties from sale of licensed products, Cashed-In Equity from sale of equity in the licensee received as part of the license consideration, and all other types of license income, such as upfront fees, annual minimum royalties, milestone payments and so forth. Detailed data were received for 94.7% of total License Income Received for all respondents, down from 98.6% in fiscal year 2001. The data are summarized in Table S-13. In fiscal year 2002, $1.005 billion or 79.4% of License Income Received was derived from Running Royalties from product sales, an increase of $159.8 million or 18.9% from $844.9 million in fiscal year 2001, which accounted for 73.2% of License Income Received in

Table S-12: Net License Income and Licenses/Options Yielding Income 1991 – 2002

	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
Number of Respondents	130	130	158	159	173	173	175	179	190	190	198	219
Net License Income (millions $)	186	248	323	360	424	514	611	725	862	1,263	1,071	1,267
Number of Respondents	130	130	158	159	173	173	175	179	190	190	198	218
Licenses/Options Yielding Income	2,711	3,377	4,198	4,534	5,396	6,163	6,974	7,460	8,308	9,059	9,707	10,866

fiscal year 2001. One hundred fifty three point three ($153.3) million dollars of the increase was reported by recurrent respondents and $6.5 million was reported by net new responders. In fiscal year 2002, $241.4 million or 19.1% of License Income Received was derived from other types of License Income Received, an increase of $62.3 million from $179.0 million in fiscal year 2001, which accounted for 15.7% of License Income Received in fiscal year 2001. Forty-three point two ($43.2) million of the increase was reported by recurrent respondents and $19.1 million was reported by net new responders. In fiscal year 2002, $20.0 million or 1.6% of License Income Received was derived from Cashed-In Equity from sale of equity in the licensee, a decrease of $94.1 million from $114.0 million in fiscal year 2002, which accounted for 10.0% of License Income Received in fiscal year 2001. This decrease is attributable to the lack of initial public offerings in fiscal year 2002 and depressed stock market conditions. Recurrent respondents reported a decline of $94.7 million in Cashed-In Equity, while net new responders reported an increase of $0.6 million.

Two hundred fourteen institutions reported that 5,853 Licenses/Options yielded Running Royalties, an increase of 768 or 15.1% more than the 5,085 reported by 179 institutions in fiscal year 2001, of which an additional 459 were reported by recurrent responders and 309 were reported by net new respondents. This figure implies that at least 5,853 products resulting from Licenses/Options are reaching the public (since some Licenses/Options are fully paid up, the actual number is undoubtedly higher). The figure also means that at least 22.4% of Active Licenses/Options and 53.9% of Licenses/Options Yielding License Income have resulted in products being on sale to the public.

Figure 25: Total License Income Received by U.S. Universities, 2002

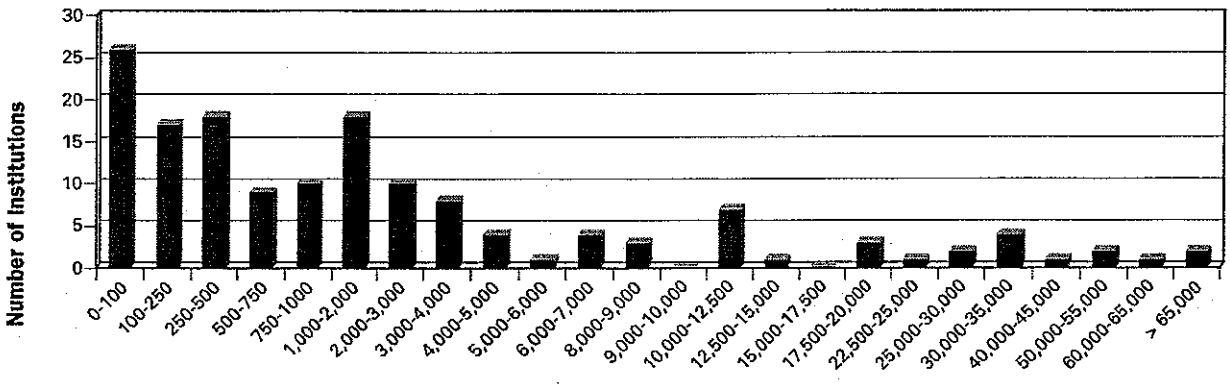


Table S-13: Source of Gross License Income in 2002: Running Royalties, Cashed-In Equity and Other

		Gross License Income Received						
FY 2002	Number of Respondents	Total	Running Royalties	% of Total	Cashed-In Equity	% of Total	Other	% of Total
U.S. Universities	150	983	787	80%	15	2%	180	18%
U.S. Hospitals & Research Institutes	30	207	151	73%	3	1%	53	26%
Canadian Institutions	31	28	21	75%	1	4%	6	21%
Patent Management Firms	1	48	46	96%	-	0%	2	4%
All Respondents	212	1,266	1,005	79%	19	2%	241	19%

Figure 27 illustrates the relative contributions of the types of income to the total reported income since 1996 when the question was first asked. Table S-12 reports the number of Licenses/Options Yielding Income for all respondents.

Sixty-one institutions reported that they had at least one License/Option that generated more than $1 million in License Income Received during fiscal year 2002, including three institutions that reported that they had ten or more Licenses/Options that each generated more than $1 million in License Income Received during fiscal year 2002. In total, 145 Licenses/Options generated more than $1 million in License Income Received during fiscal year 2002, up 14 or 10.7% from the 131 reported in fiscal year 2001. All of the increase was from net new responders. These "mega licenses"

Figure 26: Total License Income Received by U.S. Hospitals and Research Institutes, 2002

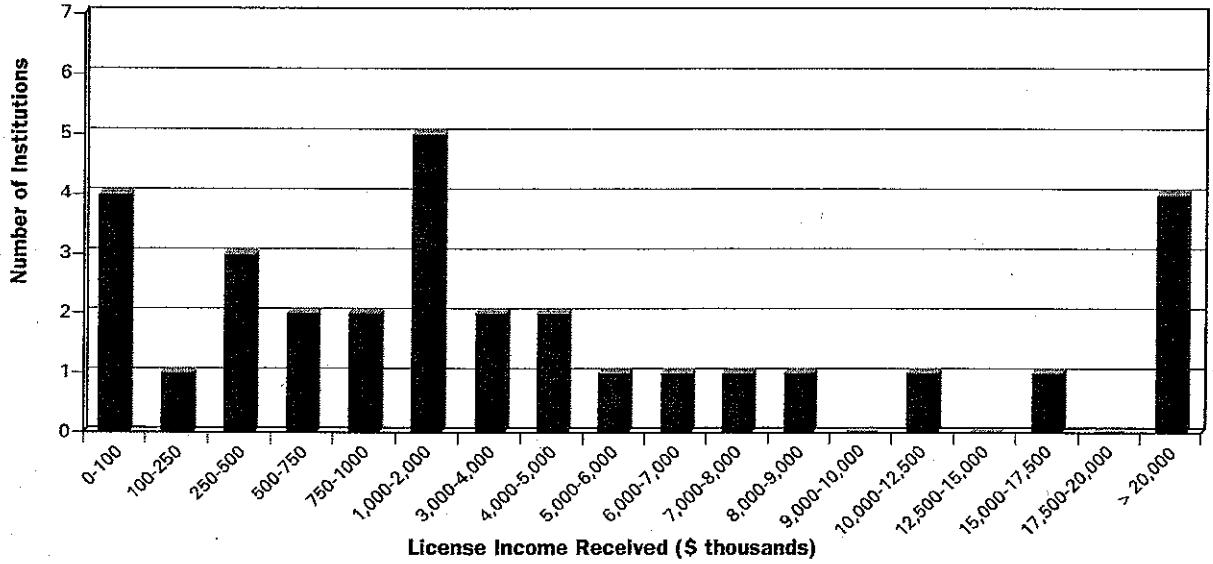


Figure 27: Gross Income Received by Income Type, All Respondents, 2002

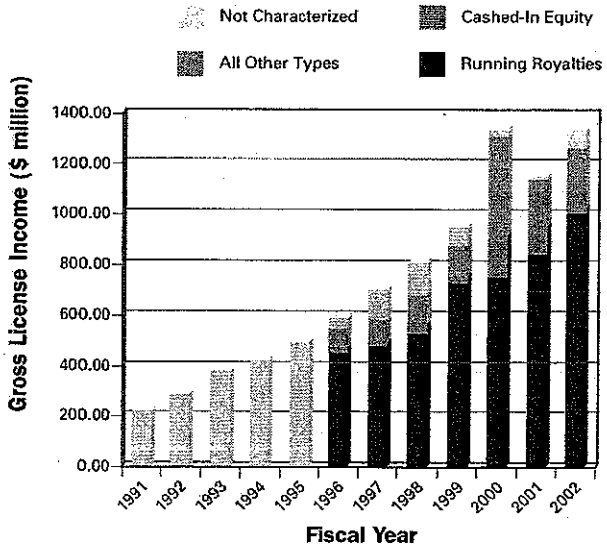
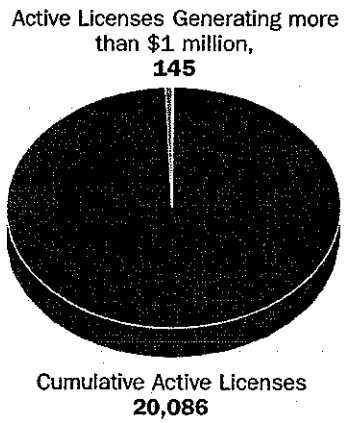


Figure 28: Active Licenses Generating More Than $1 Million in FY 2002



account for only 1.3% of all Licenses/Options Yielding Income, the same percentage as in fiscal year 2001. This is illustrated in Figure 28.

The Bayh-Dole Act requires institutions to share the proceeds of licensing federally funded inventions with inventors, with the balance, after the recovery of expenses, required to be used for research and education. In general, institutions have a single patent policy which does not distinguish between different funding sources, so income from all sources is treated the same. The institutional share is distributed according to the individual institution's policy to academic units — laboratories, department, and schools — and the institution itself.

3.4.E Research Support Linked to Licenses

Another route by which institutions benefit from technology transfer is the sponsorship of research at the institution to further develop the technology and assist in the transfer process. One hundred eighty-four institutions reported they received $247.7 million of Research Funding commitments linked to License/Option Agreements in fiscal year 2002. This figure was down $3.9 million or 5.8% from the fiscal year 2001 figure reported by 164 institutions. Recurrent responders reported a decrease of $22.3 million, while net new responders reported an additional $18.4 million. The fiscal year 2002 figure corresponds to 8.3% of all Research Expenditures: Industrial Sources, down from 9.0% in fiscal year 2001.

4.0 Company Start-Up Activity

4.1 Start-Up Information

Start-Up Companies have historically been a major part of the innovation process as established firms frequently are unable to embrace new technologies that have the potential to render their existing investments and technologies obsolete. This phenomenon remains true in the academic licensing sector and Start-Up Company activity continues to be a significant aspect of the technology licensing process.

As has been noted throughout this report, fiscal year 2002 was an extraordinarily difficult period for raising early stage funding and the number of Start-Up Companies formed fell significantly, from 494 in fiscal year 2001 to 450, a decrease of 44 or 8.9%. Among recurrent respondents, the decrease was even larger, 55, but that was offset by an additional 11 reported by net new responders. One hundred thirty-one institutions reported at least one Start-Up Company in fiscal year 2002; two institutions each reported 23 Start-Up Companies formed in fiscal year 2002. Figures 29 and 30 show the distribution in Start-Up Companies formed by U.S. universities and U.S. hospitals and research institutes, respectively.

Start-Up Companies tend to be located close to the institution from which the technology originates. In fiscal year 2002, 83.1% of Start-Up Companies were located in the same state as the institution from which they licensed their technology, down from 84.4% in fiscal year 2001.

Table S-14: Start-Up Companies Formed, 1980 – 2002

	FY 1980 to 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 1980 to 2002
Number of Institutions Reporting 1 or more	130	83	96	86	101	114	111	121	138	132	
Number of Institutions Responding to the Question	154	156	172	168	171	176	188	190	196	214	
Start-Up Companies Formed	1,169	241	223	248	333	364	344	454	494	450	4,320

Table S-15: Licenses and Start-Ups with Equity, 1995 – 2002

	FY 1995	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
Number of Institutions Reporting 1 or more	70	66	78	82	79	90	108	122
Licenses with Equity	142	167	251	272	243	372	391	443
Number of Institutions Reporting 1 or more						87	104	111
Start-Ups with Equity	NA	NA	NA	NA	NA	252	348	312

Table S-14 also shows that 4,320 Start-Up Companies have been formed since 1980. Since 1993, institutions have been asked how many of the start-ups they have previously reported as having been formed have become Non-Operational. In fiscal year 2002, 142 Start-Up Companies became Non-Operational, up 51 or 56.0% from the 91 which became Non-Operational in fiscal year 2001, of which 47 were reported by recurrent responders and four by net new responders.

Institutions have also been asked how many of the start-ups they previously reported as having been formed are still Operational. In fiscal year 2002, 2,741 were reported to be still Operational by 210 institutions of which 204 were reported by recurrent responders and 23 by net new responders. This figure is broadly consistent with a "calculated" figure of 2,822 obtained by combining the 2,514 start-ups reported by 187 institutions to still be Operational in fiscal year 2001, with the 450 new start-ups formed

Figure 29: Start-Up Companies Formed by U.S. Universities, 2002

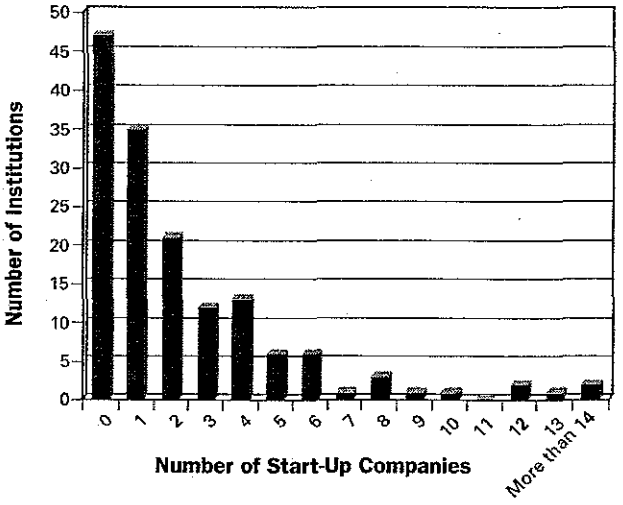


Figure 30: Start-Up Companies Formed by U.S. Hospitals and Research Institutes, 2002

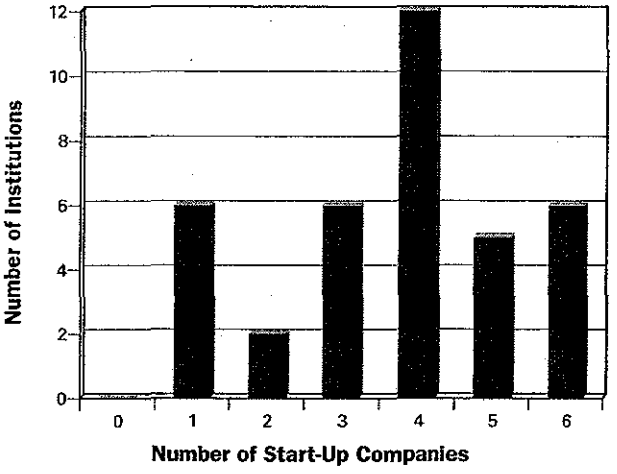


Figure 31: Start-Up Companies Formed by U.S. Universities Operational at End of FY 2002

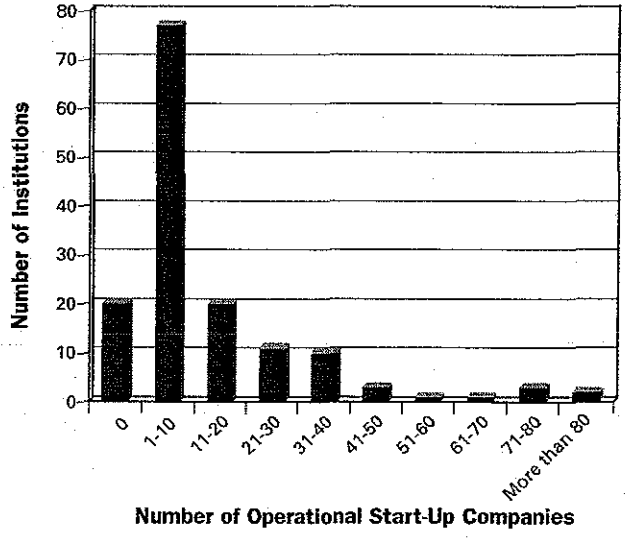
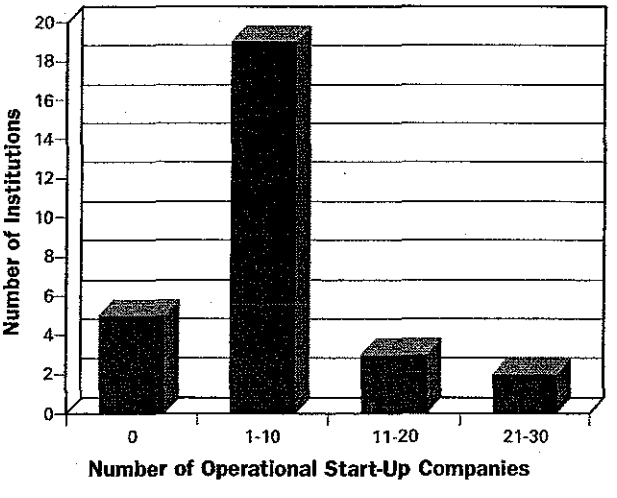


Figure 32: Start-Up Companies Formed by U.S. Hospitals and Research Institutes Operational at End of FY 2002



and the 142 start-ups which ceased to be Operational in fiscal year 2002. The 2,741 start-ups still Operational is 63.4% of the 4,320 that have been formed since 1980. This is a high survival rate for new company start-ups and approaches that experienced by the venture capital industry overall, a possibly unsurprising observation since a large proportion of university Start-Up Companies are funded by venture capital. Figures 31 and 32 show the distribution of Start-Up Companies formed by U.S. universities and U.S. hospitals and research institutes that were Operational at the end of fiscal year 2002, respectively.

4.2 Institutional Equity Holdings

Start-ups rarely have a positive cash flow during their first years of operation and providers of early stage financing are generally loath to see significant amounts of the early stage financing paid out in license fees. Therefore, Equity is often the only "currency" that Start-Up Companies have to offer licensor institutions as upfront consideration.

In fiscal year 2002, 203 institutions reported that they had granted 313 Licenses with Equity to Start-Up Companies, down 35 or 10.1% from the 348 reported in fiscal year 2001, of which a decrease of 33 was reported by recurrent responders and a decrease of two was reported by net new responders. Institutions received Equity in 69.6% of Start-Up Companies formed, down slightly from 70.4% in fiscal year 2001.

The total number of Licenses/Options with Equity was substantially higher than this, 443 granted by 218 institutions, up 52 or 13.3% from 391 License/Options with Equity granted in fiscal year 2001, of which recurrent responders reported an increase of 41 and net new responders reported an increase of 11. In fiscal year 2002, 70.7% of the licenses with equity were licenses to Start-Up Companies, whereas in fiscal year 2001, the percentage was 89.0%. In other words, the proportion of licenses with equity executed with existing Small Companies almost tripled from fiscal year 2001 to fiscal year 2002. One interpretation of these figures may be that in a tough financial climate for new venture formation, an increased number of licenses with existing Small Companies included Equity as a substitute for a cash element in the transaction in order to conserve cash for operations. In addition, the data reported in Section 3.3.B showed that existing Small Companies accounted for a substantially increased percentage of the overall licensing mix in fiscal year 2002.

5.0 Canadian Institution Activity

5.1 Respondents

Thirty-three Canadian institutions responded to the fiscal year 2002 Survey[x], an increase of six or 22.2% from the 27 that responded to the fiscal year 2001 Survey. This number is 17.6% of the 187 U.S. institutions that responded to the fiscal year 2002 Survey. The Survey has historically included all Canadian respondents in a single category. However, if the U.S. classification system were applied to Canadian respondents, five or 15.2% would be classified as hospitals/research institutes and 28 or 84.8% would be classified as universities. By comparison, 17.1% of U.S. respondents were classified as hospitals/research institutes and 82.9% were classified as universities. The breakdown between the two classes of institutions is therefore very similar in the two countries.

Canadian institutions are asked to report their financial data to the Survey in Canadian dollars. For use in the main section of the report above, the Survey translates the figures into U.S. dollars using a single, year-end exchange rate. Table C1 shows the exchange rates that have been used since the Survey started.

Financial data below are in Canadian dollars, as reported. For avoidance of doubt, the symbol "C$" is used to indicate financial figures reported in Canadian dollars. Benchmarking comparisons use figures translated into U.S. dollars, using an exchange rate of Canadian $1.570 equals U.S. $1. The symbol "$" is used to indicate figures quoted in U.S. dollars.

Table C1: Exchange Rates Used to Convert Canadian Dollars to U.S. Dollars FY 1991 – FY 2002

Year	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
C$/$U.S.	1.200	1.250	1.290	1.366	1.373	1.364	1.384	1.403	1.486	1.471	1.548	1.570

5.2 Research Support

Thirty-three Canadian institutions reported Total Research Expenditures of C$3.221 billion in fiscal year 2002, up C$436.5 million or 15.7% from the C$2.784 billion reported by 26 institutions in fiscal year 2001.

Thirty-two Canadian institutions reported Federal Research Expenditures of C$1.421 billion in fiscal year 2002, up C$99.1 million or 7.5% from the C$1.322 billion reported by 26 institutions in fiscal year 2001. This figure was 4.1% of U.S. Federal Research Expenditures of $22.190 billion, indicating that the Canadian Federal Government invests less in academic research than the U.S. Government relative to both population and gross domestic product (GDP) and reflecting the proportionately greater role of Canadian Provinces in supporting academic research. Canadian Federal Research Expenditures accounted for 44.1% of Total Research Expenditures in fiscal year 2002, compared with 62.4% in the U.S.

Historically, research expenditures reported by Canadian institutions did not include principal investigators' salaries and benefit costs, or indirect costs. In the budget of December 2001, it was announced that the federal government would start paying the indirect costs of research. The impact that this will have on overall funding levels is yet to be determined in this analysis since the financial impact will only be seen in the AUTM FY 2003 Survey results.

Thirty-one Canadian institutions reported Industrial Research Expenditures of C$407.9 million in fiscal year 2002, down C$9.8 million or 2.3% from the C$417.7 million reported by 26 institutions in fiscal year 2001. This figure was 9.6% of U.S. Federal Research Expenditures of $2.713 billion, indicating that industry invests about the same on academic research as in the U.S. relative to both population and GDP. In Canada, Industrial Research Expenditures accounted for 12.7% of Total Research Expenditures in fiscal year 2002, compared with 8.0% in the U.S. In fiscal year 2001, the Canadian figure was significantly higher, 15.0%.

5.3 Benchmarking Methodology

A number of measures can be used to compare economic parameters from different countries.

- **Population.** Population is one of the most basic factors that must be controlled for. The population of Canada as of July 2002 was 31.9 million, 11.4% of the 280.6 million persons in the U.S. at the same time.
- **GDP.** The development of a country's economy, as measured by its GDP, is another way of normalizing economic factors and takes population differences into account. According to the Organization for Economic Cooperation and Development (OECD; September 2003), Canadian GDP in 2002 was $716.7 billion, 6.9% that of the U.S. GDP in 2002 of $10,383 billion.
- **Purchasing Power.** Different countries have different costs of living and of doing business, so that a given expenditure in different countries will be expected to produce different amounts of economic output. According to the same OECD report, Canada's purchasing power parity (PPP) is 1.2 times that of the U.S., implying that the cost of doing business is less in Canada than in the U.S. and that same dollar expenditure would therefore be expected to produce 1.2 times more output in Canada than in the U.S.

In technology transfer, it is widely accepted that the appropriate benchmarking basis is the total level of academic research funding in a country (See, for instance, *Twenty Years of Academic Licensing — Royalty Income And Economic Impact, Ashley Stevens, Les Nouvelles XXXVIII No. 3, 133-140* for a review of studies of technology transfer performance which establish this metric when comparing performance between different institutions).

An Australian study, *National Survey of Research Commercialization, Year 2000,* published by the Australian Research Council, the Commonwealth Scientific and Industrial Research Organization and the National Health and Medical Research Council, proposed the use of PPPs to adjust Total Research Expenditures when carrying out international benchmarking studies. This adjustment takes into account the fact that if a country has a lower cost of living and of doing business, a given Total Research Expenditure will be expected to produce a greater quantity of research output, including intellectual property.

As discussed above, Canadian institutions reported C$3.221 billion or $2.052 billion in Total Research Expenditures in fiscal year 2002. Canadian Purchasing Power Parity Adjusted Total Research Expenditures (ATRE) was therefore $2.052 x 1.2 or $2.462 billion in fiscal year 2002. This is 7.0% of the reported U.S. Total Research Expenditures of $34.939 billion and bears the same relationship to the U.S. figure as the ratio of the two countries' GDP.

In this section, numerical figures (FTEs, Invention Disclosures, etc.) are benchmarked per $100 million ATRE, while dollar figures (License Income, Legal Expenses, etc.) are benchmarked per $1 million ATRE and are reported in U.S. dollars.

5.4 Resources

Thirty-one Canadian respondents reported 112.5 Licensing FTEs in FY 2002, up from 89 FTEs reported by 27 institutions in fiscal year 2001. The average number of Licensing FTEs per office in Canada is therefore 3.6, up from 3.3 in FY 2001, slightly lower than the 3.95 Licensing FTEs in the average U.S. office. Canadian institutions have 4.6 Licensing FTEs per $100 million ATRE, 121.5% higher than the 2.1 Licensing FTEs per $100 million ATRE for U.S. institutions.

Thirty-two Canadian respondents reported 122.2 Other FTEs in fiscal year 2002, up from 94.9 FTEs reported by 27 institutions in FY 2001. The average number of Licensing FTEs per office in Canada is therefore 3.8, up from 3.5 in fiscal year 2001, slightly lower than the 3.9 Other FTEs in the average U.S. office. Canadian institutions have 5.0 Other FTEs per $100 million ATRE, 151.6% higher than the 2.0 Other FTEs per $100 million ATRE for U.S. institutions.

5.5 Invention Disclosures and Patents

Thirty-three Canadian institutions reported receiving 1,175 Invention Disclosures in fiscal year 2002, up 242 or 25.9% from the 933 Invention Disclosures reported by 26 institutions in fiscal year 2001. Canadian institutions therefore received 47.7 Invention Disclosures per $100 million ATRE, 17.4% more than the 40.7 Invention Disclosures per $100 million ATRE reported by U.S. institutions.

Thirty-three Canadian institutions reported 422 New U.S. Patent Applications Filed in fiscal year 2002, up seven or 1.7% from the 415 New U.S. Patent Applications Filed by 26 institutions in fiscal year 2001. Canadian institutions reported 17 New Patent Applications filed per $100 million ATRE, 17.9% lower than the 20.9 New Patent Applications filed per $100 million ATRE by U.S. institutions. Canadian institutions are more selective in converting Invention Disclosures into New U.S. Patent Applications in Canada, converting 35.9% of Invention Disclosures to New U.S. Patent Applications Filed, compared with 51.4% in the US.

Thirty-two Canadian institutions reported 172 U.S. Patents Issued, up 10 or 6.2% from the 162 U.S. Patents Issued reported by 27 institutions in fiscal year 2001. This figure corresponds to 7.0 U.S. Patents Issued per $100 million ATRE, 30.0% lower than the 10.0 U.S. Patents Issued per $100 million ATRE reported by U.S. institutions.

Thirty-three Canadian institutions reported total Legal Expenses of C$10.7 million, an increase of C$2.1 million or 24.7% from the C$8.6 million reported by 27 institutions in fiscal year 2001. Canadian institutions spent $2,763 in Legal Expenses per $1 million ATRE, 48.3% less than the $5,539 Legal Expenses per $1 million ATRE reported by U.S. institutions.

Thirty-one Canadian institutions reported total Legal Expenses Reimbursed of C$4.0 million, an increase of C$358,000 or 9.8% from the C$3.7 million Legal Expenses Reimbursed reported by 26 institutions in fiscal year 2001. Canadian institutions were reimbursed for 37.8% of Total Legal Expenses in fiscal year 2002, compared with a reimbursement rate of 42.5% for U.S. institutions in fiscal year 2002.

5.6 Licensing

Thirty-two Canadian institutions reported 362 Licenses/Options Executed in fiscal year 2002, an increase of 29 or 8.7% from the 333 reported by 27 institutions in fiscal year 2001. This figure corresponds to 14.7 Licenses/Options Executed per $100 million ATRE, 21.1% higher than the 12.2 Licenses/Options Executed per $100 million ATRE reported by U.S. institutions.

Thirty-two Canadian institutions reported 1,715 Active Licenses/Options in FY 2002, an increase of 273 or 18.9% from the 1,412 reported by 27 institutions in fiscal year 2001. This figure corresponds to 69.7 Active Licenses/Options per $100 million ATRE, 1.1% higher than the 68.9 Active Licenses/Options per $100 million ATRE reported by U.S. institutions. Thirty-two Canadian institutions reported that 195 of the Licenses/Options Executed in fiscal year 2002

were exclusive, 53.9% of the total, while 167 or 46.1% of the total were Non-Exclusive. In the U.S. in fiscal year 2002, 46.5% of Licenses/Options Executed were Exclusive and 53.5% were Non-Exclusive, indicating that Exclusive Licenses are a more important part of the licensing mix in Canada than in the U.S.

Thirteen point nine percent (13.9%) of Licenses/Options Executed in fiscal year 2002 by Canadian institutions were with Start-Up Companies, a decrease from 21.0% in fiscal year 2001. Forty-one point six percent (41.6%) of Licenses/Options Executed in FY 2002 were with Small Companies, an increase from 40.2% in fiscal year 2001, while 44.5% of Licenses/Options Executed in fiscal year 2002 were with Large Companies, an increase from 33.1% in fiscal year 2001. In the U.S. in fiscal year 2002, the breakdown was 13.6% Start-Up Companies, 55.9% Small Companies and 30.5% Large Companies.

In total therefore, 55.5% of Licenses/Options Executed in fiscal year 2002 by Canadian institutions were with companies with fewer than 500 employees, a decrease from 64.9% in fiscal year 2001, whereas in the U.S. in fiscal year 2002, the corresponding figure was 71.0%.

5.7 License Income

Thirty-three Canadian institutions reported C$51.5 million in Total License Income in fiscal year 2002, a decrease of C$13.6 million or 20.9% from the C$65.1 million reported in fiscal year 2001. Total License Income was $13,322 per $100 million ATRE, 62.9% lower than the $35,940 per $100 million ATRE reported by U.S. institutions. However, this comparison needs to be made in the context of the superior performance of Canadian institutions in Start-Up Company formation, discussed in Section 5.9 below. Thirty-two Canadian institutions reported 738 Licenses Yielding Income in fiscal year 2002, up 79 or 12% from fiscal year 2001. This corresponds to 30.0 Licenses Yielding Income per $100 million ATRE, 6% more than the 28.3 Licenses Yielding Income per $100 million ATRE reported by U.S. institutions. Thirty Institutions reported 411 Licenses/Options Yielding Running Royalties, the same number as reported by 24 institutions in fiscal year 2001. This figure corresponds to 16.7 Licenses/Options Yielding Running Royalties per $100 million ATRE, 8.2% higher than the 15.4 Licenses/Options Yielding Running Royalties per $100 million ATRE reported by U.S. institutions.

License Income Paid to Other Institutions was C$1.0 million, an increase of C$367,276 or 54.9% from fiscal year 2001. Net Income was therefore C$50.5 million, a decrease of C$14.0 million or 21.7% from fiscal year 2001.

In fiscal year 2002, Running Royalties on product sales accounted for 64.9% of Total License Income, an increase from 46.7% in fiscal year 2001; Cashed-In Equity accounted for 4.3% of Total License Income, a decrease from 24.3% in fiscal year 2001; and Other accounted for 17.6% of Total License Income, down from 29% in fiscal year 2001. In fiscal year 2002, the corresponding U.S. breakdown for type of income was 79.4% Running Royalties, 1.5% Cashed-In Equity and 19.0% Other.

Six licenses yielded income over $1 million in fiscal year 2002, the same number as in fiscal year 2001.

5.8 Research Support Linked to Licenses

Twenty-seven institutions reported C$17.5 million of Research Support Linked to Licenses/Options, up C$4.3 million or 32.9% from fiscal year 2001. This accounted for 4.2% of Research Support: Industrial Sources, up from 3.2% in fiscal year 2001. In the U.S., Research Support Linked to Licenses/Options accounts for 8.7% of Research Support: Industrial Sources.

5.9 Company Start-Up Activity

Forty-nine Start-Up Companies were formed in fiscal year 2002, down 19 or 27.9% from the 69 reported in fiscal year 2001. This corresponds to 2.0 Start-Up Companies formed per $100 million ATRE, 73.8% higher than the 1.1 Start-Up Companies formed per $100 million ATRE reported by U.S. institutions. All of the Start-Up Companies were located in the same Province as the institution from which the technology was licensed. The institution received equity in 27 of these Start-Up Companies or 55.1%, as compared with 69.6% in the U.S.

Thirty-one Start-Up Companies formed in previous years became non-operational during fiscal year 2002, leaving 493 Start-Up Companies operational at the end of fiscal year 2002. This compares with 2,236 Start-Up Companies Operational in the U.S. Canadian institutions reported that 20.0 Start-Up Companies were Operational per $100 million ATRE, 212.9% higher than the 6.4 Start-Up Companies reported operational per $100 million ATRE by U.S. institu-

tions. Equally, Canadian institutions reported that 1.3 Start-Up Companies became Non-Operational per $100 million ATRE, 396.6% higher than the 0.3 Start-Up Companies which became Non-Operational per $100 million ATRE reported by U.S. institutions.

Although Canadian institutions generate more Start-Up Companies per $100 million ATRE than their U.S. counterparts, they generate lower total License Income Received per $100 Million ATRE, as was discussed in section 5.7 above. These two results are presumably inversely linked. If a technology is licensed to a Start-Up Company, from which a significant portion of the financial return will come from Cashed-In Equity, it cannot be licensed to an existing company for a return via upfront f0, milestone payments and Running Royalties. Therefore, the higher level of interest of Canadian institutions in forming Start-Up Companies likely leads to a corresponding decrease in licensing revenues. Studies by U.S. institutions have shown that Start-Up Companies make substantially greater investments in developing new technologies than either existing small companies or large companies and so have the greatest positive economic impact (see the article in *les Nouvelles* referenced in Section 5.3 above for references to these studies.)

5.10 Product Introductions

Twenty institutions reported that licensees introduced 26 products to the market in fiscal year 2002, up five or 23.8% from fiscal year 2001. Since 1998 when the question was first asked, licensees of Canadian institutions have launched 318 products. This figure equates to 12.9 per $100 million ATRE, 156.7% higher than the 5.0 products launched in the U.S. per $100 million ATRE.

Healthcare

QLT's Visudyne® Therapy — University of British Columbia

In 1981, four scientists from the University of British Columbia (UBC) founded Quadra Logic Technologies Inc. (QLT), now a global biopharmaceutical company dedicated to the discovery, development and commercialization of innovative therapies to treat cancer, eye diseases and immune disorders.

In 1987, QLT entered into research and license agreements with UBC to support Dr. David Dolphin's research of porphyrin chemistry aimed at making stable molecules capable of absorbing long wavelength visible/IR light. The resulting collaboration resulted in the introduction of Visudyne® (verteporfin) for the treatment of wet age-related macular degeneration (AMD), the leading cause of blindness in men and women over the age of 50. More than 13 million Americans over the age of 40 exhibit signs of AMD.

In fiscal year 2002, Visudyne® sales exceeded U.S. $287 million. Visudyne® therapy could be the most successful product ever in ophthalmology and could be the first ophthalmic product to reach U.S. $1 billion annual sales. (See: http://www.qltinc.com)

Levulan™ Photodynamic Therapy — Queen's University/Royal Military College

Levulan™ is a novel form of photodynamic therapy (PDT) discovered by Dr. James Kennedy of Queen's University and Dr. Roy Pottier of Royal Military College, in Kingston, Ontario.

Drs. Kennedy and Pottier became intrigued with the idea of treating cancers by selectively mimicking porphyria in tumour cells. Porphyria is a condition in which affected tissues are light-sensitive and tissue damage can result with light exposure. Their research led to the development of Levulan™ PDT for the treatment of actinic keratosis, the red, scaly precancerous skin lesions of the face and scalp common to fair-skinned individuals. The treatment has proven effective and easy to use, with no known negative side effects.

In 1991 PARTEQ Innovations licensed the technology to Deprenyl Research Ltd., which spun out DUSA Pharmaceuticals to commercialize Levulan™. The product was approved for use in the U.S. in 1999 and in Canada in late 2001.

Public Health

University of Alberta 'Spreads' Diseases Through Innovative Teaching Tool

University students across North America are sharing a handful of vicious micro-organisms, including West Nile virus, Ebola and Anthrax, all originating from the University of Alberta. But university authorities appear pleased with the national media attention to the "outbreak" of about 100 diseases.

That's because doctors, medical students and instructors are sharing trading cards depicting the diseases and symptoms, not the actual microbes. The novel educational tool employs the sports trading cards format to teach medical microbiology to university stu-

dents. Dr. Mark Peppler, associate professor in the Department of Medical Microbiology and Immunology at the University of Alberta, developed the tool based on his childhood passion for sports cards.

The American Society for Microbiology Press liked the idea so much they created 5,000 boxes of MicrobeCards in 2002 (50% sold before shipping to suppliers). Retailers range from university bookstores to Amazon.com. A sequel is in the works. (See: http://homepage.mac.com/markpeppler/microbe.html or Amazon.com.)

Software

DBMiner — Simon Fraser University

Major innovations in data mining techniques and algorithms developed by Dr. Jiawei Han and his team (Intelligent Database Systems Research Laboratory, Simon Fraser University (SFU)) led to the creation of DBMiner Technology Inc. (1997), a SFU Start-Up Company. DBMiner developed the world's first server applications providing powerful, highly scalable association and sequence mining capabilities for the Microsoft SQL Server 2000 Analysis Platform. DBMiner applications analyze customer profiles and preferences from large volumes of Web log data, providing analyses of up-selling (a customer purchasing a VCR today is a potential DVD player buyer later), cross-selling (purchase of two related products such as a TV and VCR), profit optimization, e-commerce transactions, customer support, defect correlations, and even suspicious activities. Microsoft chose "DBMiner Insight" as a powerful, scalable and easy-to-use analytics solutions program on Microsoft's SQL Server and a Marketing Alliance for the Microsoft Product Platform & Partnership Agreement was signed in June 2002. (See http://www.dbminer.com/about/fullstory.html).

5.11 Summary of Canadian Results

The use of Purchasing Parity Power Adjusted Total Research Expenditures (ATRE's) to compare Canadian performance metrics to U.S. metrics brings into stark relief the differences in the practice of technology transfer in the two countries.

Per $100 million ATRE, Canada

- Employs 121.5% more Licensing FTE's and 151.6% more support FTE's;
- Generates 17.4% more Invention Disclosures;
- Filed 17.9% fewer New U.S. Patent Applications;
- Converted 35.9% of Invention Disclosures into New U.S. Patent Applications, compared with 51.4% in the US;
- Received 30.0% fewer U.S. Patents Issued;
- Spent 48.3% less on Legal Fees Expended, but received roughly the same rate of reimbursement as in the U.S.;
- Executed 21.1% more Licenses/Options, but had around the same number of Active Licenses/Options;
- Executed a somewhat higher percentage of exclusive Licenses/Options Executed;
- Executed about the same percentage of Licenses/Options Executed with Start-Up Companies, somewhat less with existing Small Companies and somewhat more with Large Companies;
- Received 62.9% less License Income Received;
- Created 73.8% more Start-Up Companies;
- Had 212.9% more Start-Up Companies still Operational at the end of fiscal year 2002;
- Saw 396.6% more Start-Up Companies become Non-Operational during fiscal year 2002; and
- Launched 156.7% more products than the U.S.

The picture that emerges is one of greater people intensiveness, greater selectivity and cost effectiveness on the patent side, a substantially higher importance of start-up companies, which have a higher survival rate but which went out of business at a disproportionately higher rate than in fiscal year 2002 in Canada than in the U.S. and greater success at getting products to market.

6.0 Concluding Remarks

The results presented above vividly illustrate both the long-term nature of technology transfer and the short-term impacts on it of overall economic conditions.

The early stage, high technology sector experienced an unprecedented difficult set of conditions over the past three years. The NASDAQ peaked on March 10, 2000 at 5,048.62, and has since seen a decline of around 60%, wiping out $5 trillion in stock market value. Venture capital investments declined for 12 straight quarters beginning in the second quarter of 2000, and didn't begin to show any sign of recovery until the second quarter of 2003. Venture capital partnerships raised half the amount of capital in calendar year 2002, $21.2 billion, versus the $42.9 billion raised in calendar year 2001.

These effects were felt in both the high technology sector — computers, software and telecommunications — and biotechnology sector, the sectors in which the majority of academic inventions find their application. As this report is being written (October 2003), the first glimmerings of an opening of the initial public offering (IPO) window are being seen for three years. IPOs provide liquidity to venture capitalists and their limited partner investors and are the essential final step in the innovation cycle, allowing high risk capital to be freed-up to start development of the next round of new ideas.

The FY 2002 Licensing Survey results reflect the very difficult conditions that university licensing professionals experienced in fiscal year 2002. While federal funding for research continued to climb strongly, industrial funding grew at only one third that rate and research funding linked to licenses and options, a major incentive for academic scientists to participate in the technology transfer process, declined. The share of transactions with both Start-Up Companies and Large Companies declined significantly from fiscal year 2001. However, Small Companies stepped up to the plate to take up the shortfall.

The absence of an IPO window and the low level of stock prices resulted in a drastic fall in license income from stock liquidation.

Reflecting the difficult conditions in the venture capital industry, the number of new start-ups declined significantly and the number of start-ups going out of business increased particularly sharply.

Yet despite these difficult circumstances, universities continued to reap the rewards of the transactions completed and the partnerships forged in the two decades since the passage of Bayh-Dole and continued to increase investment in technology transfer for the long term. Universities invested in increased human resources in their technology transfer offices. Invention disclosures continued to increase, as did the number of patents filed. The increase in legal expenses exceeded the growth in both research funding and invention disclosures and patent filings. An area for attention is that these investments did not result in an increase in the number of patents issued, though this may reflect a one to two year lag from decisions made in the past. Transactions increased, reversing a decline from the prior year reported in last year's Survey.

Total royalty income continued to climb, despite a substantial decline in equity liquidation. The proportion of royalty income coming from Running Royalties on product sales continued to climb, reflecting the important role of the products that have been developed over the past two decades. Royalty income, though still less than 3% of total research funding, is now providing a significant source of unrestricted funding for investment in research and education at the relatively small number of institutions that have been fortunate enough to hit a home run. Continuing that analogy, in the vast majority of cases though technology transfer remains a game of bunt singles, not grand slams.

Survey Participants

AUTM's Board of Trustees expresses appreciation to the fiscal year 2002 Licensing Survey participants listed below.

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Allegheny-Singer Research Institute
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Auburn University
Baylor College of Medicine
Beth Israel Deaconess Medical Center
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Brandeis University
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Brown University Research Foundation
Burnham Institute
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California Pacific Medical Center Research Institute
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Center for Blood Research
Children's Hospital, Boston
Children's Hospital, Cincinnati
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