行政院及所屬各機關出國報告

（出國類別：實習）

美國聯邦技術移轉機制實習報告

服務機關：經濟部技術處
出國人 職　　稱：科員
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出國地區：美國
出國期間：中華民國 90 年 11 月 14 日至 12 月 2 日
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參加聯技會赴美實習技術移轉美國聯邦技術移轉機制實習報告

主辦機關:

經濟部

聯絡人／電話:

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出國人員:

王昱凱　經濟部　技術處　科員

出國類別: 實習

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關鍵詞:

內容摘要: 一九八〇年代美國許多重要產業表現不如日本及歐州，使得美國國會及政府部門開始重視如何建構國家整體創新體系。其發現要達成強化國家國際競爭力，是需要聯邦實驗室、大學與產業界充分合作，建立綿密的研究合作及技術移轉體系，將美國政府資助的研究計畫成果導入美國境內實質運用，進而提升產業技術水準，創造就業機會，於是美國國會通過Bayh-Dole act 和Stevenson-Wydler act二項法案，而後亦以此二法案爲基礎，訂定或修正一系列有關技術移轉之法規。而本次實習之目的，即是爲瞭解美國政府機構是如何規劃聯邦資助成果之技術移轉、在技術移轉中政府扮演之角色、及大學如何有效執行技術移轉事宜，以提供我國未來技術移轉政策及實務運作上之參考。 實習建議包括積極將我國國家研究機構及大學納入產業支援體系、將知識管理及跨領域人才之培育納入我國教育政策內、建立研究人員流動機制、建立檢視研究機構與產業間均衡發展之機制、及鼓勵及創造技術移轉相關功能之機構及產業的加入等。

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目　　錄

實習目的

一九八〇年代美國許多重要產業表現不如日本及歐州，使得美國國會及政府部門開始重視如何建構國家整體創新體系。其發現要達成強化國家國際競爭力，是需要聯邦實驗室、大學與產業界充分合作，建立綿密的研究合作及技術移轉體系，將美國政府資助的研究計畫成果導入美國境內實質運用，進而提升產業技術水準，創造就業機會，於是美國國會通過 Bayh-Dole act 和 Stevenson-Wydler act 二項法案，而後亦以此二法案為基礎，訂定或修正一系列有關技術移轉之法規。

而我國在八十八年一月二十日公布施行「科學技術基本法」後，又訂定「政府科學技術研究發展成果歸屬及運用辦法」及「經濟部科學技術委託或補助研究發展計畫研發成果歸屬及運用辦法」等技術移轉相關法規，期達成美國聯邦技術移轉機制之績效。而本次實習之目的，即是為瞭解美國政府機構是如何規劃聯邦資助成果之技術移轉、在技術移轉中政府扮演之角色、及大學如何有效執行技術移轉事宜，以提供我國未來技術移轉政策及實務運作上之參考。

實習建議

謹將實習建議說明如下：

一、積極將我國國家研究機構、大學納入產業支援體系

美國 Bay-Dole Act 及 Stevenson-Wydler Act 等一系列技術移轉法規成功的主要關鍵之一，是將原本僅從事學術研究及教學的大學，納入產業支援體系內，藉由大學教授、研究生等研究人力，從事與商品化相關之技術研究；以此為源頭後，帶動產業界直接運用(leverage)學校研究能量，進而帶動產學合作研發風氣；而國家研究機構亦從原本擔負的使命，加入協助業者之角色。而大學與國家研究機構帶進產業之研究成果，確實是美國新經濟成果之主要動力。因此，在我國產業面臨轉型及升級的今天，建立有效的管道，將國家研究機構與大學能量釋放予產業界，是為當今科技政策應考量的重要措施。

而為推動此目的之達成，在施行政策上可考量將單位技術移轉之績效納為國家科技研發預算分配之參考指標；而為改變大學教授及國家研究機構研究人員之行為，除應有適當的成果獎金獎勵外，更應將技術移轉績效納為教授升等或研究人員工作績效衡量範圍內。

二、推動國家研究機構及研究型大學成立技術移轉辦公室

由於研究人員的專業係在從事研究工作，對涉及研發成果管理所需的專利佈局策略，以何種型態之智慧財產權保護其發明，甚至與產業界技術移轉之價格訂定，技術移轉合約擬訂等，均需要技術、管理及法律專業人員予以負責，因此，為達成將我國國家研究機構、大學納入產業支援體系，則必須推動國家研究機構及研究型大學成立技術移轉辦公室。

三、將知識管理及跨領域人才之培育納入我國教育政策內

在參訪的過程中，觀察到技術移轉人員所必須具備的工作技能，除各技術專業領域外，亦須法律及管理技能，以處理智慧財產權管理、運用等事宜，因此學校技轉辦公室的技轉人員，多為擁有專業博士學位後，再取得法學碩士學位。而在我國目前的教育體系下，對因應新環境的調整機制較為薄弱，對智慧財產權等知識管理、運用及跨領域之人才培育尚嫌不足，故建議應將跨領域人才之培育納入我國教育政策整體規劃內。

四、建立人員流動機制

美國大學及聯邦機構主要係從事基礎研究，不似我國已有工業技術研究院等研究機構，係以從事研究發展，再將成果技術移轉予業界為使命之機構，而此類研究機構與產業界互動頻煩，如何保持適當的人員流動機制，是我國技術移轉政策所面臨的問題。

研究發展研究機構之研發人員透過適當的管道流動至產業界，是可將研發能量帶至產業界，從事實質商品化工作，強化產業競爭力。但此流動亦涉及如何達成「平衡」問題，如大量的研發人員受業界提供的股票選擇權等財務誘因所吸引移轉至業界，將使研究機構的研發能量大量流失，無法進行長期性之前瞻創新研發工作。

又業界倘若不以合法管道向研發機構移轉技術及招募研發人員，以高薪方式挖角吸納研究人員，或研發人員私自運用研發成果自行創業，將使政府資助之研究計畫成果無法廣為業界使用，而失去政府資助研發計畫之目的。因此如何設計平衡研發人員流動之機制，乃為一重要議題，以下謹將建議說明如下：

（一）、由研究機構建立人員交流及輔導創業機制

適當的研發人員流動，乃是國家競爭力之重要源頭，在美國的矽谷實習過程中，相關受訪人員均表示美國政府並無相關獎勵措施，矽谷的興起乃是史丹佛大學及加州柏克萊大學培育大量人才，以供產業界所需。而如何創造人員交流及輔導創業機制，如對創業有興趣之研究人員，提供公司營運管理及取得資金等相關創業資訊，或建立留職停薪機制，鼓勵研究人員至產業界嘗試，均是研究機構應予重視之處。

（二）、建立研發人員流動管理機制

1. 計畫重要研究人員應對政府資助研究計畫執行予以適當承諾

以往科技專案執行上，發生少數計畫之研究人員，在研究計畫尚未結束前，就受到業界的挖角或自行創業，而影響計畫研發成果之產出，並造成政府資源投入之損失。因此如何設計研發成果與研究成果能予分離之機制，讓研究人員能適當流動，研發成果能留於研究機構乃為重要課題。而建議解決措施之一，即是重要計畫人員在計畫執行前，即能承諾如無適當理由，應留任至計畫結束。

2. 研發人員離職後一定期限內之成果應歸屬或無償授權原單位使用及再授權

在美國因保護智慧財產權的觀念較為普遍，研究人員通常均會遵守相關規範；且研究機構係偏向從事基礎研究，類此問題較少發生，若個案發生亦即以法律途徑解決，因此無類此之管理機制。惟在參考美國業界與學校之合作研發契約中，業界通常會規範學校研發人員於研究計畫結束後六個月內之研發成果，亦屬該合作標的範圍內。將此作法修正，規範研究機構之研發人員離職後一定期限內之成果應歸屬或無償授權原單位使用及再授權之權利，係考量研發成果不可能是在短期間產生，離職後一定期限之成果產出應是接續原於研究機構服務之研究，依公平原則原研究機構應擁有一定權利，方可使政府資源之投入，能獲得公平的運用。

（三）、建立研發人員涉及技術移轉之利益揭露制度

研發成果係由研究人員所發明創作，如何運用亦是研發人員最為知悉，而以往科技專案亦有技轉廠商控訴研發人員自行創業或至其他技轉廠家服務之不公平現象。因此，建立一透明機制，若有研發人員利益涉及技術移轉事宜者，應有一套機制予以調合，以達成兼具產業效益及社會公平原則。

五、以國有研究設施設備之支持民間研發

在我國由於政府資助之研究計畫其所購置之研究設施設備係屬國有，須依國有財產法之規定辦理；而國有財產法之設計，係以防止弊端為考量，對如何有效運用國有研究設施設備支持民間研發，無法完全配合。如國有財產法第二十八條規範，主管機關或管理機關原則上對於公用財產不得為任何處分或擅為收益。

反觀美國在此部分則較為彈性，其合作研究發展契約(CRADAs)即以提供設備、人員等資源與產業界合作研發，促使產業投入資源從事研發。而我國科技專案以往研究設施設備之購置，係以個別專案提報購置，缺乏研究單位內整體考量，建議應朝向建立實驗室觀念建構研究設施設備，以達一方面能節省資源，另一方面又能提供產業界整體

之服務。

六、應建立檢視研究機構與產業間均衡發展之機制

在本次實習過程，各受訪單位均一致強調均衡(Balance)的觀念。此觀念包含大學等研究單位原有使命與任務與技術移轉之均衡，教授從事技術移轉與原教學、研究之均衡等，是否因重視商品化研究而忽視基礎研究等。而檢視的指標，則包含大學教授的論文公開發表是否因此減少等。

而在我國，由於有從事應用研究之研究機構，如何保持其與產業間之均衡發展，更是一重要的議題。如應用研究之人員流動率是否過高，而影響原研究機構之能量建立，或造成對原產業的結構變化，是應行檢視的重要標的。

七、研究機構技術移轉由外部審視機制朝向內部自主

以往，重要科技專案的技術移轉策略與執行，即是我國產業政策的具體施行措施，是由政府所主導，但成果歸屬研究單位後，此角色

則已較為淡化，然為兼顧公平、公正、公開程序，亦要求有產、官、學、研等專家組成之委員會，對技術移轉價格、條件、方式等作一審視與決定，是以供給者決定技術移轉條件，此作法之優點是可充分考量整體環境，但缺點則是缺乏彈性調整。

而美國原即為強調市場競爭，政府運作上僅維持市場運作，並無特定資源配置之產業政策。而美國大學在從事技術移轉時，是由內部作成決策，並與廠商進行協商談判，決定技術移轉事宜，以充分彈性地回應廠商的需求，而我國在成果歸屬研究機構一定期間後，俟研究機構建立完整機制，應亦可考量免除外部委員會審視之要求。

八、應進行科技專案運作及技術移轉成功模式之研究

次微米計畫之執行是過去科技專案重大的成功案例之一。此計畫係由工業技術研究院組成研發團隊，至美國 RCA 公司移轉技術，再由政府主導，有計畫性的將團隊及技術移至產業界，成立　聯華電子公司，造就我國半導體產業在世界占有一席之地。而今，因應我國產業已轉向「以民間產業界主導，政府提供輔助資源」及推動研發成果歸屬研究機構後，如何建立成功的科技專案運作及技術移轉模式，在

與產業界接觸的介面上充分提供必要的資源，是應予重視的課題。

九、科技專案計畫執行策略、技術移轉策略及績效指標作緊密的結合

在各個受訪大學，均非常重視重大技術成果(Big Hit)之產出，而此重大技術成果之產出，並非單單技術移轉策略所致，而是在研究過程中即重視相關智慧財產權的研究與分析，而產出具原創性的研發成果，而在績效指標的衡量上，亦應因應調整，增列統計重大技術成果其成果移轉績效，及評估各研發成果所帶來的附加價值，以因應知識經濟時代之需。

十、鼓勵及創造技術移轉相關功能之機構及產業的加入

在美國聯邦資助研發成果之技術移轉成功關鍵之一，即是具有綿密的輔助功能或協助。如立法成立聯邦實驗室聯盟，以從事聯邦實驗室之技術交流與訓練；大學技術經理人協會(Association of University Technology Managers, Inc.; AUTM)提供大學技術移轉之教育訓練、成員間經驗分享及績效統計；NASA 也建立商業化技術網絡，將美國分為六大地域，分別建立各地域技術移轉中心；此外，亦

有大學成立之研發成果管理及推廣機構、技術移轉獲得股權之管理機構或類似創投公司等機構的參與，以活絡其技術移轉活動。而我國尚在推動科學技術基本法初期，許多類似功能之機構及產業尚在孕育，政府部門應予以鼓勵與重視。

十一、大學及研究機構社會此類非營利組織之再定位

除原先之使命及接受政府資助從事研究外，大學及研究機構也應積極推動與產業界合作研發的機會。除此之外，大學及研究機構是否應提供資金投資自有技術成立新創公司；否應參考美國大學規範所收取之單一公司股權，應設有一定上限原則，是否應規避進入公司董事會；對技術移轉或投資涉及單位研發人員之公司，是否應有特別規範等，均將遷動大學及研究機構非營利組織之再定位。

十二、境外實施原則應隨產業政策調整為重視廠商在我國之研發投入

目前經濟部科學技術委託或補助研究發展計畫研發成果歸屬及運用辦法規定，科技專案研發成果原則應在我國管轄區域內製造或使用，例外情況則應報經濟部核准。但為配合我國在全球布局的定位，

是朝向以建立研發中心，必要的生產製造應視產業需求，作全球性的布局，而移至具生產成本優勢國家或地區生產。

而國家資助之研發成果係運用人民之稅收，理應限制在我國生產製造，以帶動我國就業及經濟成長。惟為配合全球布局之需求，應將政策考量調整，對技術移轉廠商之境外生產製造予以鬆綁，惟於技術移轉條件上，調整為要求廠商之技術移轉營運書中，就後續研發之投入，應在我國進行，以帶動我國成為全球研發中心。

實習行程

10:00 A.M., 15th Nov., 2001 Director Katharine Ku Associate Linda Chao Stanford University Office of Technology Licensing 900 Welch Road, Suite 350 Palo Alto, CA 94304 e-mail: shawn.harlan@stanford.edu Phone: (650) 723-0651 Fax: (650) 725-7295
11:00 A.M., 16th Nov., 2001 Attorney Lucas S. Chang Attorney Y. Vicky Chou Attorney Ariel Reich HellerEhrman law office tel.: 650.324.7100 fax: 650.324.0638 e-mail: Lchang@hewm.com web: http://www.hewm.com Silicon Valley 275 Middlefield Road Menlo Park, CA 94025-3506
19th Nov.,2001 8:30 A.M. Contact: Karen Kelly AT&T Lab in Menlo Park (650)463-7083 75 Willow Road Menlo Park, CA 10:00 A.M. Contact: Queenie Zee Silicon Graphics Inc. Mountain View, CA (650)933-1840 1:00 P.M. MIT-Stanford Venture Lab Contact: Masue Kanno (408)213-0557 Mountain View, CA

10:00 A.M. 20th Nov., 2001 **Tim Wan** **tel.: (510)587-6071** **fax: (510)587-6090** **e-mail:** tim.wan@ucop.edu **web: http://www.ucop.edu/ott/** **Office of Technology Transfer** **Office of President** **1111 Franklin Street, 5th Floor** **Oakland, CA 94607-5200**
09:00 A.M. 21st Nov.,2001 **Director** **Rosanne Dutton** **Office of Technology Licensing** **tel.: 213-743-2282** **fax: 213-744-1832** **e-mail:** dutton@usc.edu **web: hhtp://www.usc.edu/dept/Patents_copyrights**
10:00 A.M. 26th Nov.,2001 **Technology Transfer Officer** **Rita C. Manak** **Office of Intellectual Property Administration** **tel: (310)794-0558** **fax:(310)794-0638** **e-mail:** rmanak@resadmin.ucla.edu **10920 Wilshire Boulevard, Suite 1200** **Los Angeles, CA 90024-1406**
10:00 A.M. 27th Nov.,2001 **Policy Analyst** **Sharon Yun** **Technology Policy Analyst** **David Brantley** **Technology Policy Analyst** **Mark Boroush** **Office of International Technology** **Technology Administration** **US Department of Commerce** **Washington, DC 20230 USA** **Tel: 202/482-6814** **Fax: 202/219-3310** **e-mail: sharon.yun@ta.doc.gov**

08:30 A.M. 28th Nov., 2001 Attorney Francis J. Gorman Gorman & Williams Attorneys at Law A Partnership of Professional Corporations FJGORMAN@GANDWLAW.COM WWW.GRANDWLAW.COM 2 North Charles St. Suite 750 Baltimore, MD 21201 Tel:410-528-0600 Fax:410-528-0602
29th and 30th Nov., 2001 Attending Industry & Research Institution Collaborative Relationship Conference American Conference Institute The Fairmont Copley Plaza Hotel, 138 St. James Ave, Boston, MA, United States

實習內容

以下僅就美國聯邦技術移轉法規、美國政府機關在技術移轉扮演之角色及執行現況、美國大學技術移轉辦公室如何作業、美國大學從事技術移轉之重要管理制度、美國大學技術移轉新機制等分別說明如下

美國聯邦技術移轉法規

美國聯邦政府資助研究發展之成果歸屬及運用係以規範非營利機構(大學)及小型企業之 Bayh-Dole Act 和規範聯邦實驗室之 Stevenson-Wydler Act 二項法案為基礎，以下謹將此二關鍵性法案摘要說明如下：

Bayh-Dole Act 摘要說明如下：

一、 規範非營利機構(大學)及小型企業接受聯邦政府經費從事研發後之研發成果歸屬及運用等事宜。

二、 非營利機構(大學)及小型企業應向聯邦機關報告研發成果產出，並於研發成果產出後一定期間內擁有選擇權，選擇是否擁有該研發成果。

三、 非營利機構(大學)及小型企業應於一定期間提出專利申請。

四、 研發成果取得者原則上應於美國國內實質運用以符合美國產業優先原則。

五、 研發成果取得者應定期向聯邦機關報告成果運用情形。

六、 對成果運用未符立法意旨之狀況，聯邦機關擁有介入權予以調

和。

七、 非營利機構(大學)必須符合分配成果運用收入予發明人、剩餘成果運用收入應作研發及教育用途、及優先技術移轉小型企業之原則。

Stevenson-Wydler Act 摘要說明如下：

一、 要求聯邦實驗室應成立研究及技術應用辦公室(Office of Research and Technology Applications, ORTA)，配置一定人力，並將年度研究經費一定比率分配予此辦公室，以從事技術移轉工作。

二、 建立合作研究發展契約(Cooperative Research and Development Agreement, CRADAs)，以標準化契約及簡化行政方式，建立聯邦實驗室提供非資金以外的資源與業者共同研發。

三、 研發成果運用以非專屬授權為原則，專屬授權則必須有公開程序，且成果運用應符合美國產業優先原則。

四、 聯邦實驗室應建立研發人員獎勵制度。

美國政府機關在技術移轉扮演之角色及執行現況

在與美國商務部科技政策辦公室的訪談中瞭解，美國政府部門在立法中已將此政策目的明確地表示，聯邦實驗室及大學瞭解其角色後，藉由立法授權化(Decentrize)由聯邦實驗室及大學視市場需求，決定專屬授權或非專屬授權等條件，自由彈性地與產業界洽談技術移轉事宜，並藉由聯邦實驗室契約文件的簡化及標準化，增進廠商合作

或技術移轉之意願。

雖各政府機構有不同的作法，如國防部對涉及國防機密的技術具有不同的處理方式，然原則上美國政府機構是不涉及實際從事技術移轉，而是扮演督導達成政策目的的角色。而為達成督導的功能，主要是透過報告繳交的要求及介入權的行使二項措施。

介入權(March-in Right)機制的設計，乃是美國政府將聯邦經費資助所產生的研發成果歸屬予民間後，為確保該研發成果能確實產生公共利益，乃在 Bayh-Dole Act 上設計的防衛措施，以下謹將該機制說明如下：

一、 規範標的為接受聯邦經費資助並簽訂契約所產生之任何研發成果。

二、 規範對象為與政府簽訂資助契約之相對人、研發成果受讓人或專屬被授權人。

三、 如有符合下列行使要件者，聯邦政府認為介入權行使是為必要者，得將已歸屬民間之研發成果以非專屬、部分專屬授權、或專屬授權等方式，授權予其他研發成果運用需求者：

(一)、在合理期間內，未採取或預期將不採取有效步驟，以達成研發成果之實際運用。

(二)、基於公共衛生或安全需求者。

(三)、研發成果取得者、受讓人、或專屬被授權人無法達成聯邦法令規定之公共運用目的者。

（四）、研發成果取得者、受讓人、或專屬被授權人違反美國產業優先原則或美國境內實質運用原則者。

而介入權之行使程序，係規定於 37 CFR 401.6，以下謹將該程序說明如下：

一、 當聯邦機關收到資訊發現有涉及應行使介入權之情況者，在發動介入權程序前，將通知契約相對人，並以非正式方式繼續蒐集相關資訊。

二、 在收到資訊的六十天內，聯邦機關必須決定是進入行使介入權的程序，或通知契約相對人將不進入程序。

三、 進入介入權程序的開始，必須以書面通知契約相對人表達聯邦機關正考慮介入權的行使。

四、 收到通知三十天內，契約相對人可提出反對之陳述意見。

五、 藉由專家委員會、陳述意見證明文件、及與相關證人的資訊提供，完成事實調查程序。

六、 在事實調查完成九十天內，必須作成介入權行使與否的決定通知。

發動介入權行使程序的個案並不多，但美國在一九九七年即有一個案，即 CellPro 公司請求國家衛生研究院行使介入權，將國家衛生研究院資助約翰霍普金斯大學(Johns Hopkins University)所得之一項研發成果移轉予該公司，因為約翰霍普金斯大學及其專屬授權之 Baxter Healthcare 公司並未積極將該技術商品化，而基於公共衛生或安全需求因素，要求介入權之行使。

該個案最後決定雖否決 CellPro 公司的請求，但也促使 Baxter Healthcare 公司承諾將加速將該技術予以商品化，並引發國會、聯邦機關及學術單位對此議題之重視，而對技術移轉廠商是否將研發成果實際商品化的資訊掌握更為重視。

另由與美國商務部科技政策辦公室訪談及其提供的資料(TECH TRANSFER 2000:MAKING PARTNERSHIPS WORK)中，歸納其技術移轉之執行現況如下：

一、將提升產業競爭力與各政府機構使命相結合

對部分政府機構而言，從他們的研發成果發展新產品或新服務是達成機構使命的重要部分，以美國國家衛生研究院為例，由其資助之研發成果發展新藥，將可達成增進公共健康的使命。但對另一些的政府機構而言，商品化研究成果或許對達成機構使命沒有直接的關係，但對擴大研究經驗等確有極大的貢獻，如美國國防部推動軍民通用技術的技術移轉，達成擴大成果使用者，將對此類技術的成本控制產生助益。最後一類的政府機構，研發成果的商品化與機構使命只有很小的相關性，但其研發成果產出的新產品，卻可能具有極大的商業潛力，如我國的中研院應屬此類。

二、給予產業界更多協助以接觸適合合作或技術移轉的研究機構

企業，特別是中小企業並無多餘人力配置以搜尋適當的研究機構

進行研發合作或技術移轉，而通常是基於既有的人脈關係或地域性，來尋找合作的研究機構。但以現在網際網路的便捷，政府機構應可建構一個整合性的系統，以連結相關政府機構網站及資料庫，為產業界提供一次購足(One-Stop-Shopping)的服務。

以美國現行運作為例，由於許多中小企業並不瞭解各聯邦實驗室所擁有的技術專長與能量，因此，除透過各聯邦實驗室網站的建置外，成立聯邦實驗室聯盟(Federal Laboratory Consortium, FLC)，透過聯邦實驗室聯盟網站的整合功能，成為一入口網站，提供所有聯邦實驗室的最新可移轉技術，以達成業者一次購足的需求外；另聯邦實驗室聯盟提供的新聞報及區域技術移轉服務人員，都可協助廠商尋求最適切的技術項目。

三、政府機構及聯邦實驗室應更重視如何管理及運用智慧財產權以達成技術移轉

Stevenson-Wydler act 和 Bayh-Dole act 的立法構想，是預期聯邦實驗室及大學所擁有的基礎技術能量可透過立法，移轉至產業界進一步商品化，而成為國家競爭力的重要來源之一。

以業者的角度來看聯邦實驗室可提供的技術移轉功能，是依不同技術屬性等不同而有所調整。如有些廠商是想取得智慧財產權，但有些廠商想要取得聯邦實驗室的能量，有時並非著眼於獲取智慧財產權，而是想要取得非智慧財產權的經驗及技術的分享。所以廠商向聯邦實驗室技轉的標的，須視不同技術屬性等而定，如以生技或製藥產

業為例，廠商向國家衛生研究院請求技術移轉，是為發明新藥或新療法，因此取得智慧財產權是技轉的重點；但對檢測認證性質的技術而言，廠商是為獲取經驗分享，以改善產品安全或妥適率，則無必要取得智慧財產權。

以聯邦實驗室的角度來看其技術移轉的功能，則著眼於藉由從事技術移轉，達成其使命與任務。因此，技術移轉是採取公開的論文發表、非專屬授權、或專屬授權等方式，是考量採取哪種方式最能達成其單位的使命及任務。因此同時考量業者及聯邦實驗室雙方的需求，採取不同的智慧財產權管理及運用模式，是成功技術移轉的主要關鍵因素。

四、合作研究發展契約(CRADAs)可有效地配合產業界的需求

Stevenson-Wydler act 的立法重點之一，是藉由授權各聯邦實驗室可逕行與廠商簽訂 CRADAs 合約，無須再報請上級政府機關核准，以簡化行政流程，增進效率。合作研究發展契約(Cooperative Research and Development Agreement, CRADAs)係規範美國聯邦實驗室得與其他聯邦機關、州政府或地方政府、工業組織、公共及私人基金會、非營利研究機構及其他第三人簽訂此契約，由接受並運用由合作相對人所提供的資金、人員、服務、及設施設備等財產，並由聯邦實驗室提供人員、服務、及設施設備等財產，以共同進行研究。

在 Stevenson-Wydler Act 的合作研究發展契約(CRADAs)章節中(Sec.3710a.(b)(3)(C))並明文規範，聯邦實驗室同意現職或離職人

員可從事其在聯邦實驗室所發明成果之商品化活動，以配合產業界需求。

五、屬聯邦及非屬聯邦政府研發成果規定運用不同易造成業者之困擾

Bayh-Dole Act 係規範非屬聯邦政府擁有成果之單位，如大學、非營利機構及中小企業接受聯邦經費補助之成果歸屬及運用規範；而 Stevenson-Wydler Act 則規範聯邦實驗室之成果運用等規範。由於此二法規規定不同，造成業者困擾，以專屬授權為例，Bayh-Dole Act 僅要求境內實施外，並無其他規定；而 Stevenson-Wydler Act 則規定成果運用以非專屬為原則，若須採用專屬授權必須符合下列規定：

（一）、執行單位必須先公告，對特定研發成果將採專屬性或部分專屬性授權給予公眾評述機會（即反對以專屬授權作為技術移轉之方式）。

（二）、為符合政府及公眾利益，對申請者將研發成果帶入實際運用的開發構想、規劃及能力必須加以審查。

（三）、執行單位所訂之專屬性授權條件應為該研發成果實際運用所為之「合理且必要之條件」。

執行單位所訂之專屬性授權條件及範圍不得逾越為激勵該研發成果實際運用所為之條件。因部分研發成果具有多重應用性，而申請廠商可能僅具單一應用之能力，為使研發成果能充分應用，必要時應對專屬性授權之範圍加以限制。然同為聯邦資助之成果，卻有不同運用方式，將使業者產生困擾。

六、要求研發成果境內實施已對國際性企業產生困擾

美國 Bayh-Dole Act 規定，研發成果若要以專屬性授權方式運用者，必須符合美國產業優先原則。亦即，專屬被授權人同意，在美國境內實質地利用該研發成果製造產品，但若美國國內無此商業化環境，經聯邦機關核可，方可免除此限制。

報告中亦提及，廠商對目前以面臨國際佈局，無法在授權時即決定生產地、政府應注重研發過程是在美國境內進行而非關切生產製造是否在美國境內進行、及聯邦機關對境外實施缺乏一統一作法造成廠商困擾。

七、政府機構應發展一套有效衡量技術移轉績效的指標

績效指標的建立目的，是為衡量實際運作情形是否符合當初的立法目的，並依其結果適時採取必要的修正措施。而美國國會的立法目的，是期望藉由新技術導入產業界，而產生國內新的經濟活動，創造國內新的就業機會，並強化聯邦實驗室研發能量，及對產業界的支援能力，以達成提升美國國際競爭力的最終目的。

美國在立法初期的績效重點，是評估投入面的指標，如合作研究發展契約 CRADA 契約數等，而後逐漸重視成果產生數、專利申請數、授權家數、權利金額、創造產值、創造就業量等產出面指標之統計。而由於研發績效的展現，其期程通常長於預算年度或計畫期程，甚至

計畫結束數年後才有重大的績效產出，因此造成績效難以精確衡量。

美國大學技術移轉辦公室如何作業

美國較具研究性質之大學，通常會其組織內設置技術移轉辦公室，以推動技術移轉相關事宜。以下謹將此次實習與各大學技術移轉辦公室訪談摘要、大學技術移轉辦公室提供之資訊及作業，擇要說明如下。

一、與各大學技術移轉辦公室訪談摘要

◎就大學研發人員未揭露其研發成果而逕行將該成果帶至產業界之問題，是否有相關機制予以管理部分。由於美國大學均以從是基礎研究為主，不似我國有從事產業技術研究之研究機構，而有整個研發團隊離職非經授權逕行運用研發成果之情事，因此，其在機制的建立上，亦僅為研究紀錄簿及成果揭露的要求。

而美國對智慧財產權保障的觀念較為普及，研發人員亦清楚非法運用他人智慧財產權之法律責任，及不在職務上揭露其發明，將來在申請專利時列明發明人之法律責任。而史丹佛大學技術移轉辦公室亦指出，解決此問題的方式是應訴諸法律訴訟，而該大學過去亦有聯邦機關發現此情事，而要求史丹佛大學提出訴訟之個案發生。

◎對大學研究人員發明之研發成果是否繼續協助研發人員提供資金

等資源，促其成立新創公司部分，是為一公共政策的議題，不同的大學各持不同之見解與態度。

在與美國商務部科技辦公室與談中，其指出，聯邦的立法目的是要創造新的工作機會，促進經濟成長，且為鼓勵競爭的形成，而研發人員投入產業後之成功，亦須有其他因素的配合，對此抱持樂觀其成的態度，而各聯邦機關會有不同之作法，作為主掌技術移轉法規之商業部，亦會持續監督，以保持產業及學術機構發展之平衡。

而南加州大學技術移轉辦公室主任表示，學校協助研發人員創業，從僅提供創業相關資訊至實質提供資金，係各大學各有不同作法，以芝加哥大學及哥倫比亞大學為例，均實質提供資金協助，而南加州大學目前的作法，則僅提供創業教授有關創投資金等相關資訊。

◎各大學在技術移轉實務運作上如何符合美國產業優先原則及小型企業優先原則部分。所謂美國產業優先原則是指運用研發成果所作成的商品，欲在美國市場進行銷售，則必須是在美國境內實施製造，若該研發成果運用作成之商品，是銷售至美國以外的市場，則不受此限制。此部分由於我國產業均以外銷為導向，不宜直接類比適用。

而經與各大學技術移轉辦公室訪談發現，其均相當清楚立法的目的是要協助地區產業之發展，因此行銷推廣對象，則以大學所在

周邊之廠商為主，而為至於如何符合小型企業優先原則部分，亦是以行銷推廣對象為小型企業方式，來達成法規上之要求。

◎在瞭解並比較美國大學與我國研究機構在技術移轉之執行部分。在與加州大學洛杉磯分校技術移轉辦公室訪談中得知，其在技術移轉決策上，並不像我國有外部委員會的參與。

在我國科技專案技術移轉項目的計價，是須經由外部委員會審視決定，而加州大學洛杉磯分校作法，則是由內部設立一套標準，依不同技術屬性，設定不同訂價，如生技技術移轉後，通常需要較長期間的開發，因此在早期的權利金要求較低，基準約為 4%；而軟體部分，則考量產品生命週期較短，權利金基準約為 10%。由技術移轉人員依此基準與廠商議價，因此，最終技術移轉價格的決定，經由與廠商談判議價後所決定。

加州大學洛杉磯分校在技術移轉程序上，並不似我國科技專案規定應同時以網際網路、登報、成果說明會等公開方式進行技術移轉。其作法上是將技術項目置於網際網路上，再由技術移轉人員主動與可能技轉之廠商接洽，而以目前經驗，通常一項技術僅有一至二家廠商有興趣，在與廠商接觸後再決定技術移轉策略與條件。

而在技術移轉條件的決定上，亦是由與廠商洽談後，決定授與專屬授權或非專屬授權等條件。在史丹佛大學之作法上則稍有不同，其在與廠商接觸前，通常會評估技術屬性及市場狀況後，決

定是以專屬或非專屬授權方式從事技術移轉。而我國之科技專案則具產業政策導向，由研究機構視產業結構，擬具合適之技術移轉策略後，由外部專家委員會審視，廠商角色則為技術移轉條件之接受者。

而加州大學洛杉磯分校在技術移轉的對象選擇上，是廠商技術移轉能力考量大於技術移轉價格的高低。至於其無登報公開機制，是否會有專屬授權予廠商後，又有其他廠商要求技術移轉之情事時，其表示此狀況並不常發生，惟其專屬授權廠商是擁有再授權之權利，因此，廠商可請專屬授權廠商予以再授權。

◎對於其技術項目是否可授權其他國家廠商(如臺灣等)，程序上是否有所不同部分。各大學技術移轉辦公室均表示，對其他國家之廠商若要求授權，均表示歡迎，且程序上並無不同，只是其行銷推廣僅限於當地產業，故較少有國外廠商要求技術移轉，而史丹佛大學技術移轉辦公室也指出，曾有技術移轉予臺灣廠商之個案。

二、美國大學技術移轉辦公室提供之資訊

在與史丹佛大學技術移轉辦公室訪談中，其表示其在網路所建構的資訊，是一技術移轉辦公室應具備之功能，即是有效的作為大學教職員等研究人員與產業界接觸之有效介面所應提供的資訊，以下僅將其提供大學發明人及產業界之資訊說明如下：

對發明人提供的資訊：

◎處理發明之標準作業程序

◎技術移轉辦公室及發明人

專利政策

版權政策

有形研究財產政策

發明之所有權政策

權利金分配政策

交由第三者從事授權之政策

外界資助研究涉及運用史丹佛大學既有發明之政策

史丹佛大學對技術移轉事宜授權技術移轉辦公室處理之授權政策

美國政府資助之研究成果政策

有形材料之移轉契約規範

利益衝突規範

技術授權獲得股權之規範

◎專利規範

申請專利之決定因素

專利發明人之決定

專利律師審視前準備、審視會議、及審視後注意事項

◎對發明人提供的重要資源

研究紀錄之建議事項

專利及版權相關契約條文

發明評估檢查表

發明揭露制式表格

文件範例

研究資金資訊提供

創業相關資訊提供

◎填寫發明揭露表格各項次之解釋

對產業界提供的資訊：

◎技術移轉程序

◎技術移轉政策

智慧財產權政策

對教職員與授權公司具特定關係之授權政策

有形材料之移轉契約規範

醫療技術評估契約

史丹佛大學商標使用原則

◎對業界提供的重要資源

使用制式契約條款的技術項目

廠商留下有興趣之技術項目以利隨時提供最新之可移轉技術

版權使用許可及保密契約

新公司創辦計畫書大綱、材料移轉契約、專屬授權、非專屬授權、

◎及軟體授權契約書

◎可移轉技術項目線上查詢

◎史丹佛大學技術移轉辦公室與發明者之互動

三、美國大學技術移轉辦公室之作業程序及與產業界研商之議程

擁有一套完善之技術移轉標準作業程序，將可使發明人、產業界

及技術移轉辦公室職員等參與人員瞭解不同階段應準備或從事何項工作，以下謹介紹史丹佛大學技術移轉辦公室的標準作業程序說明如下：

（一）、由發明人填交發明及技術揭露表格予技術移轉辦公室，以作成發明紀錄，此紀錄內容包含發明人及資助者等。

（二）、技術移轉辦公室完成登錄並指派專人負責管理該成果。

（三）、技術移轉辦公室負責專人將與發明人面談，確認該發明的生產可行性、可能的運用範圍及市場，以規劃授權策略。不同的發明應研擬不同的授權策略，如研究成果為基礎科學工具，則需廣泛的運用，因此應以非專屬授權方式為授權策略；相對的，若該成果後續需要公司大量的資源投入，則應以專屬授權方式為授權策略，方能對被授權公司產生誘因。

（四）、基於以上資訊，技術移轉辦公室負責該特定發明之專人將決定是否保留該研發成果並申請專利。由於專利申請成本相當高（約為六千至一萬美元），因此，多僅就該發明已有公司有興趣技轉者，方申請專利。

（五）、技術移轉辦公室負責專人進行該發明之行銷，與潛在被授權者就雙方共同目標之達成，進行談判。由於每個技轉個案技轉雙方的需求等狀況均不同，因此技轉的條件是相當有彈性的，是由個案談判協商所決定。

（六）、與被授權公司簽訂技術移轉契約，被授權公司應定期提交該技轉技術相關之財務及發展報告，在授權的期間內，技術移轉辦公室負責專人並應檢視被授權人的成果

運用績效。

（七）、由技術移轉辦公室負責收取技術移轉收入，並於會計年度結束時，依下列比率分配收入：

1. 先行分配技術移轉收入之 15%以供技術移轉辦公室運作；另其他如專利申請等無法由被授權人攤還之直接費用，亦應先行由收入支應。

2. 剩餘的淨收入再各分配三分之一給予發明人、發明人系所、及學校；而發明人系所及學校所收取的收入，僅可供作教育及研究之用。

（八）、技術移轉辦公室亦應隨環境變化，負責檢討並重新評估技轉條件；而技術移轉雙方，於技轉契約存續期間，均可視情況要求修改契約條款。

史丹佛大學技術移轉辦公室評估、行銷及授權其所擁有的技術。技轉辦公室的使命是有效的移轉技術，以造福社會大眾，同時並收取技術移轉所產生的收入，以供學校教育及研究所需。以下謹將史丹佛大學與產業界研商之議程說明如下：

（一）、確認被授權人的目標及需求

（二）、表達史丹佛大學的目標及需求，包含：

1. 商品化成果以供社會大眾所用並創造社會利益

2. 分享成果收益以供學校持續研究

3. 管理潛在的利益衝突

4. 賠償責任

（三）、授權選擇的注意事項有：

1. 授權範圍的界定

2. 專屬授權或非專屬授權

3. 授權期限

4. 被授權人投入規劃包含營運計畫、資金投入規劃、及經營管理團隊

5. 授權費用支付條件

（四）、授權契約通常包含的條款有：

1. 授權範圍的界定，包含成果應用及附著於商品

2. 專屬授權或非專屬授權

3. 授權期限

4. 是否給予再授權的權利及再授權應用的收入繳交

5. 權利金給付條件，含第一次給付期定義、每年最低給付額、營業額比率之決定、及以股權方式給予

（五）、被授權人對商品化時程之承諾

1. 在某特定期間前完成雛形

2. 在某特定期間前完成生產線

3. 在某特定期間前應開始銷售

美國大學從事技術移轉之重要管理制度

此部分主要係請各參訪美國大學技術移轉辦公室說明並提供我國目前在管理機制較欠缺之技術移轉收取股權政策、職務衝突政策、技術移轉之利益衝突指導方針、及大學對投資新創公司涉及其教職員之政策。

一、技術移轉收取股權政策

為鼓勵研發成果實際運用，謀取公眾利益，以收取股權作為技術移轉對價乃是一積極之作法來達成此目的。因研發成果由研究機構移轉至業界，進而進行商品化等過程，涉及後續階段的成本投入與風險負擔，而在技術移轉時即向業者收取現金為對價，將造成新創企業或規模較小中小企業之財務負擔，並影響企業後續資源之投入。因此，研究機構以收取股權作為技術移轉之對價，一方面可減輕企業之成本負擔；另一方面，亦表現對此研發成果之信心，而願共同承擔部分風險。

以下謹將加州大學技術移轉收取股權政策之主要規範說明如下：

（一）、應在公平、公正、及公開之原則下進行。

（二）、因技術移轉所持有之股權應不超過該企業股權 10%為原則。

（三）、不論持股比例為何，加州大學均不可尋求或接受擔任董事，或是行使股東會議之投票權。

（四）、當涉及將技術移轉收取之股權分配予研發人員時可採：

1. 協助研發人員直接向被技轉企業取得股權。

2. 由加州大學取得股權，並由校內財務部門以其專業，負責股權管理及處分等相關事宜；而研發人員可收取到適當的股權比例或轉換成等值之現金。

二、職務衝突政策

學校的教職員應將其時間的智力貢獻給學校從事校內之研究及教學，但由於教職員亦有機會從事校外顧問、公共服務及其他校外活動，致使忽略校內職責，產生職務上的衝突，而需平衡校內及校外的活動。史丹佛大學規範教職員從事個人校外顧問活動不得超過一定時間（每季超過十三天），或定義全職教職員主要的專業工作並不是為史丹佛大學等情況，則為職務上的衝突。

三、技術移轉之利益衝突指導方針

由於加州大學是一所州立大學，因此必須遵循 The Political Reform Act of 1974 對加州公務人員在職權行使應能公正行使，不受其本身財務利益，或給予公務人員財務協助者之財務利益所影響。據此，加州大學訂定技術移轉之利益衝突指導方針。以下謹將規範架構說明如下：

（一）、以技術移轉人員及涉及技術移轉之研發人員為規範對象。

（二）、明確定義應行利益迴避時的個人財務利益要件標準。

（三）、明確定義技術移轉人員或研發人員在何種情況下，是為「作成」技術移轉決策。

（四）、明確定義技術移轉人員或研發人員在何種情況下，是為「參與作成」技術移轉決策。

（五）、明確定義技術移轉人員或研發人員在何種情況下，是試圖以其職位影響技術移轉決策。

（六）、明確定義在何種情況下，一定之技術指導是不被視為參

與或影響技術移轉決策之進行。

（七）、技術移轉人員及研發人員應自行利益迴避之作法。

（八）、利益迴避後負責管理該成果技術移轉之機制設計。

（九）、研發人員涉及技術移轉決策利益衝突之機制設計。

（十）、要求研發人員必須填報特定表格以揭露其利益。

（十一）若研發人員並未填報該特定表格以揭露其利益，且已參與或將參與技術移轉，則技術移轉人員可決定由另一無利益衝突之人員，進行技術移轉決策之檢視。

四、大學對投資新創公司涉及其教職員之政策

以史丹佛大學為例，每年都會投資一部份的資金在發展新技術的新創公司上，但有時史丹佛大學的教職員亦有股權投資在該公司，如此情況將會產生潛在或實質上的利益衝突，但是如果符合遵循的情況下，史丹佛大學仍將會投資該新創公司：

（一）、史丹佛大學對投資涉及史丹佛教職員的新創公司將須視史丹佛管理公司執行長的建議，由教務長視個案逐案核准。假如新創公司尋求授權該涉及的教職員的發明以從事商品化的行為時，則此授權必須經諮詢副教務長及研發長的意見後，由相關系所主任及院長核准。

（二）、史丹佛大學不擔任主動參與公司新創公司運作的角色。

（三）、史丹佛大學投資不超過該新創公司股權的 10%。

（四）、史丹佛大學職員不擔任該新創公司的董事或任何職位；另在公開發行前，在史丹佛大學從事投資時點，職務相

關職員亦不得擁有該新創公司的個人股權。

美國大學技術移轉新機制

技術移轉係有不同之態樣，如透過期刊論文發表、舉辦相關成果發表會或研討會、對廠商之技術輔導、研發人員交換或互訪、對廠商進行非專屬授權或專屬授權、成立新創公司等不同方式，以下謹說明加州大學以具國際性視野為著眼之「加州大學國際技術延伸計畫」，以作為我國靈活運用不同技術移轉模式之參考。

在 2000 年六月，加州大學技術移轉辦公室開始執行國際技術延伸計畫(International Technology Outreach)。此計畫的主要目的，是尋求加州大學以外，而能與加州大學產生互補性(complementary)的技術或研發人員進行配對，以建構更完整的技術或專利組合，或激起雙方研發人員能有更進一步的合作研究。

加州大學會有此項計畫之產生，是因為其注意到國際間，不論在國家層級架構下進行的合作研究，或是在國際間研發機構之研發合作，關係均越來越密切及重要。而傳統的模式，是組合不同研究機構之研發人員，而期待最後能產生具價值的專利，或甚能成立新創公司；而加州大學認為更具效率及目標導向的作法，是合作的開始，就是著重在專利的組合或是新創公司的成立。

加州大學認為此項計畫是跳脫傳統的作法，是一種嶄新的商業模式。在實務運作上，是先藉由研究機構內專利組合的分析，尋找出具

互補性的研發成果後，在簽訂保密的協定下，再安排雙方的研發人員作進一步的接觸，而接觸後若能創造出新的專利，即安排申請此項專利。

加州大學期待藉此計畫的執行，能運用(leverage)全球卓越的大學或研究機構能量，與其進行合作研究。而合作方式通常是以簽訂備忘錄為開始，再依不同機構之能量，尋求建立不同的合作模式。

如與國立新加坡大學的合作中，亦邀請新加坡政府單位國家科學及技術局(National Science and Technology Board of Singapore)及新加坡私人創投資金的加入；而在合作的內容中，除尋求雙方互補性技術的結合外，亦就雙方之教育學程進行交流。

加州大學預期此項計畫將可產生下列之效益：

一、就共同發展之專利組合產生綜效
二、多方獲取研究經費的支持
三、獲得合作雙方國內之創投資金及種子基金等之支持
四、在國際發展規劃下，協助新創企業的成立

附錄一

US University Patenting and Licensing: Historical Evolution and Recent Trends

David C. Mowery
Haas School of Business
U.C. Berkeley

Presented at National Academy of Sciences workshop
"The Effects of University Patenting & Licensing on
Commercialization and Research"
April 19, 2001 in Washington DC

Outline

- Overview of US university patenting prior to 1980.
- Bayh-Dole and other developments during the 1980s.
- Trends during the 1990s in patenting and licensing.
- Unanswered questions and concerns.

The pre-WWII era

- Frederick Cottrell, a UC Berkeley professor and patentholder, founded the Research Corporation in 1912 to manage university patents and support scientific research.
- University patenting drew on research collaboration with industry in a number of sectors.
- Considerable ambivalence within U.S. universities over a direct university role in management of patenting, licensing.

Frederick Cottrell on University Licensing

A certain minimum amount of protection is usually felt necessary by any manufacturing concern before it will invest in machinery or other equipment, to say nothing of the advertising necessary to put a new invention on the market. Thus a number of meritorious patents given to the public absolutely freely by their inventors have never come upon the market chiefly because "what is everybody's business is nobody's business." (1912)

A danger was involved, especially should the experiment prove highly profitable to the university and lead to a general emulation of the plan. University trustees are continually seeking for funds and in direct proportion to the success of our experiment its repetition might be expected elsewhere . . . the danger this suggested was the possibility of growing commercialism and competition between institutions and an accompanying tendency for secrecy in scientific work. (1932)

The postwar era

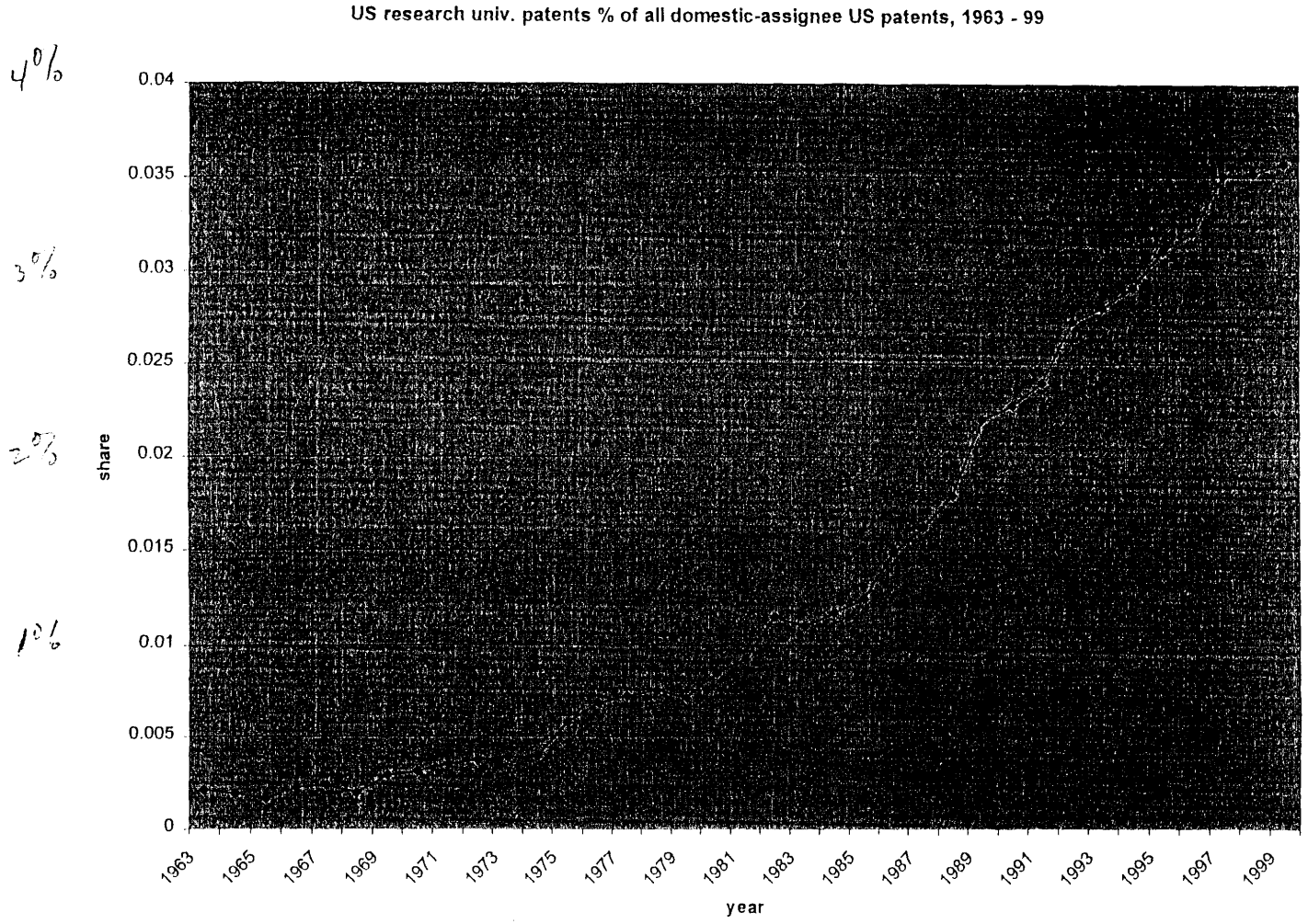
- Growth in federal funding of university research during & after WWII led a number of federal agencies to require formal patent policies at universities conducting federally sponsored research.
- By the late 1950s, most research universities had adopted formal policies.
  - But at least some of these policies, especially in medical schools, discourage or prohibit patenting.
  - Many universities "outsource" patent and licensing management to entities such as the Research Corp.
  - Public universities appear to be more active in direct management of patenting and licensing.

University patenting grows more rapidly during and after the 1970s

- US universities' share of overall US patenting is stable at roughly 0.2% during 1949-63.
- Universities account for 0.3% of US domestically assigned patents in 1970 and 3.6% in 1999, a 12-fold increase in share that considerably exceeds growth in university share of US R&D performance from 12% in 1970 to 14% in 1999.
- Private universities' share of US university patenting more than triples during 1960-80, growing from 14% in 1960 to 39% in 1970; 45% in 1980; and 39% in 1999.

University patenting during & after the 1970s (2)

- Biomedical technologies' share of US university patents increases from 11% of research university patents in 1971 to 48% in 1997. NIH share of federally funded university R&D grows from 37% to 56% during 1971-97.
- Universities become more active managers of patenting & licensing during the 1970s, at the expense of the Research Corporation, among other entities.


US research univ. patents % of all domestic-assignee US patents, 1963 - 99
4%
3%
2%
1%
0.04
0.035
0.03
0.025
0.02
0.015
0.01
0.005
0
share
1963
1965
1967
1969
1971
1973
1975
1977
1979
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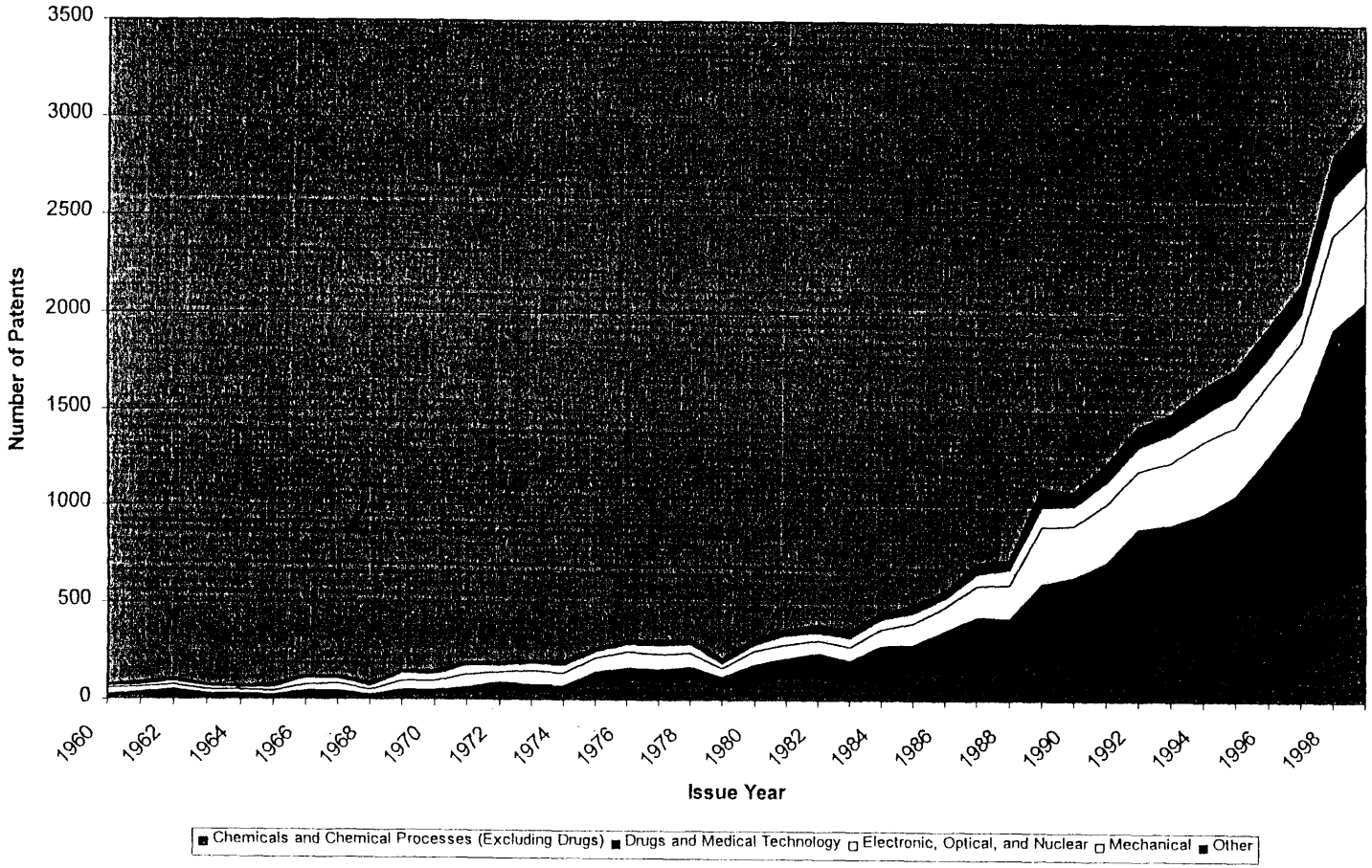
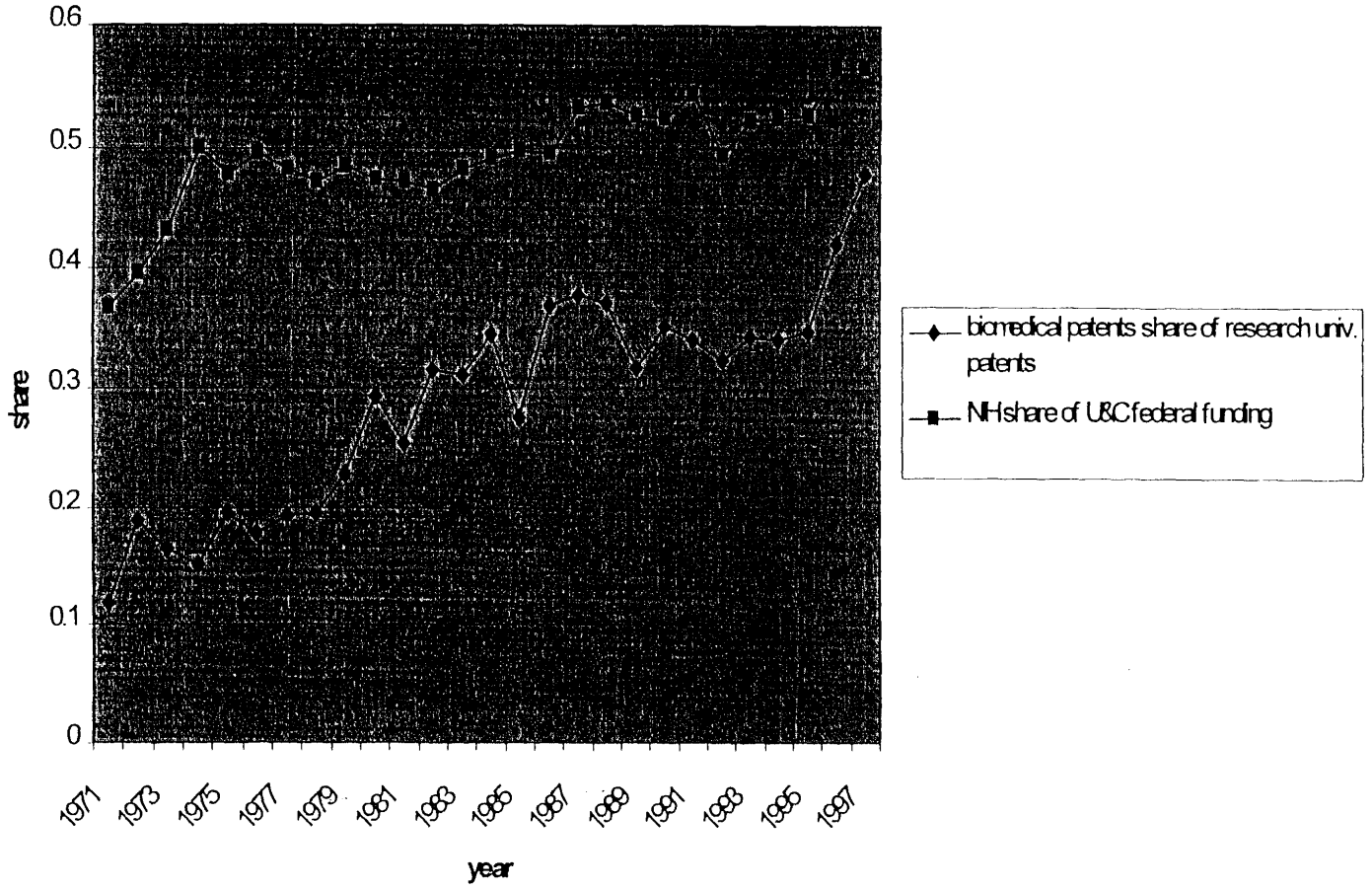
US Research University Patents and R&D Performance, 1963-99

Technology Field of Carnegie University Patents, 1960-1999



Biomedical patents and NIH funding, 1971-9



The Bayh-Dole Act of 1980

- Passed in 1980 to encourage commercial development of federally funded inventions in university and government labs.
- The Act enabled institutions to obtain patents on inventions and to license these to private parties, including exclusive licenses.
- Bayh-Dole replaced a complex web of Institutional Patent Agreements between individual federal funding agencies and individual universities.
- University patenting, growing prior to 1980, accelerated after 1980 (Research university share of US patents grows from 0.7% in 1979 to 3.6% by 1999).

Other developments during the 1970s and 1980s

- ***Diamond v. Chakrabarty***: Life forms are deemed patentable by the US Supreme Court in 1980.
- Creation of the CAFC, 1982.
- Other federal actions strengthen intellectual property protection in domestic, international economy during the 1980s.
- "War on Cancer" spurs research in molecular biology.

The "effects" of Bayh-Dole

- We observe growth in university patenting after 1980: Is this a direct result of Bayh-Dole?
- Examine Stanford and UC, both of which were active patenters and licensors, before & after 1980.
- Compare their licensing income with that of Columbia, a major post-1980 "entrant."
- Look at patterns of entry into patenting after 1980.

"Before & after" Bayh-Dole at the University of California and Stanford

- Growth in annual invention disclosures at both uinversities accelerated before 1980.
- Biomedical portion of overall disclosures also increased before 1980.
- At both institutions, biomedical inventions' share of patenting and licensing income begins to grow before 1980.
- Bayh-Dole affected patenting and licensing; but patenting and licensing, especially in biomedical technologies, was growing before the Act. Bayh-Dole only 1 of several important factors.

Licensing income at Columbia, UC, and Stanford

- Gross licensing income (constant $$) grew significantly during 1970-1995 at Stanford, UC (1985-1995 at Columbia).
  - 50-fold growth at UC, FY1970-95.
  - 200-fold growth at Stanford, FY 1970-95.
  - 60-fold growth at Columbia, FY 1985-95.
- Top 5 licenses generate a large proportion of gross income at all 3 universities.
- Biomedical licenses account for a large proportion of top 5 earners at all 3 universities.
- By 1995, the license portfolios of the "entrant" and the two "incumbents" closely resemble one another.

Selected Data on University of California, Stanford University, and Columbia University Licensing Income, FY1970-95

UC	FY1970	FY1975	FY1980	FY1985	FY1990	FY1995
Gross income (1992 dollars: 000s)	1140.	1470.	2113.	3914.	13240.	58556.
Gross income from top 5 earners (1992 dollars: 000s)	899.	1074.	1083.	1855.	7229.	38665.
share of gross income from top 5 earners (%)	7	7	5	4	5	6
share of income of top 5 earners associated with biomedical inventions (%)	3	1	5	4	9	10
share of income of top 5 earners associated with agricultural inventions (%)	5	7	4	6	0	
Stanford		FY7				
Gross income (1992 dollars: 000s)	180.	842.	1084.	4890.	14757.	35833.
Gross income from top 5 earners (1992 dollars: 000s)		579.	937.	3360.	11202.	30285.
share of gross income from top 5 earners (%)		6	8	6	7	8
share of income of top 5 earners associated with biomedical inventions (%)		8	4	6	8	9
Columbia						
Gross income (1992 dollars: 000s)				542.	6903.	31790.
Gross income from top 5 earners (1992 dollars: 000s)				535.	6366.	29935.
share of gross income from top 5 earners (%)				9	9	9
share of income of top 5 earners associated with biomedical inventions (%)				8	8	9

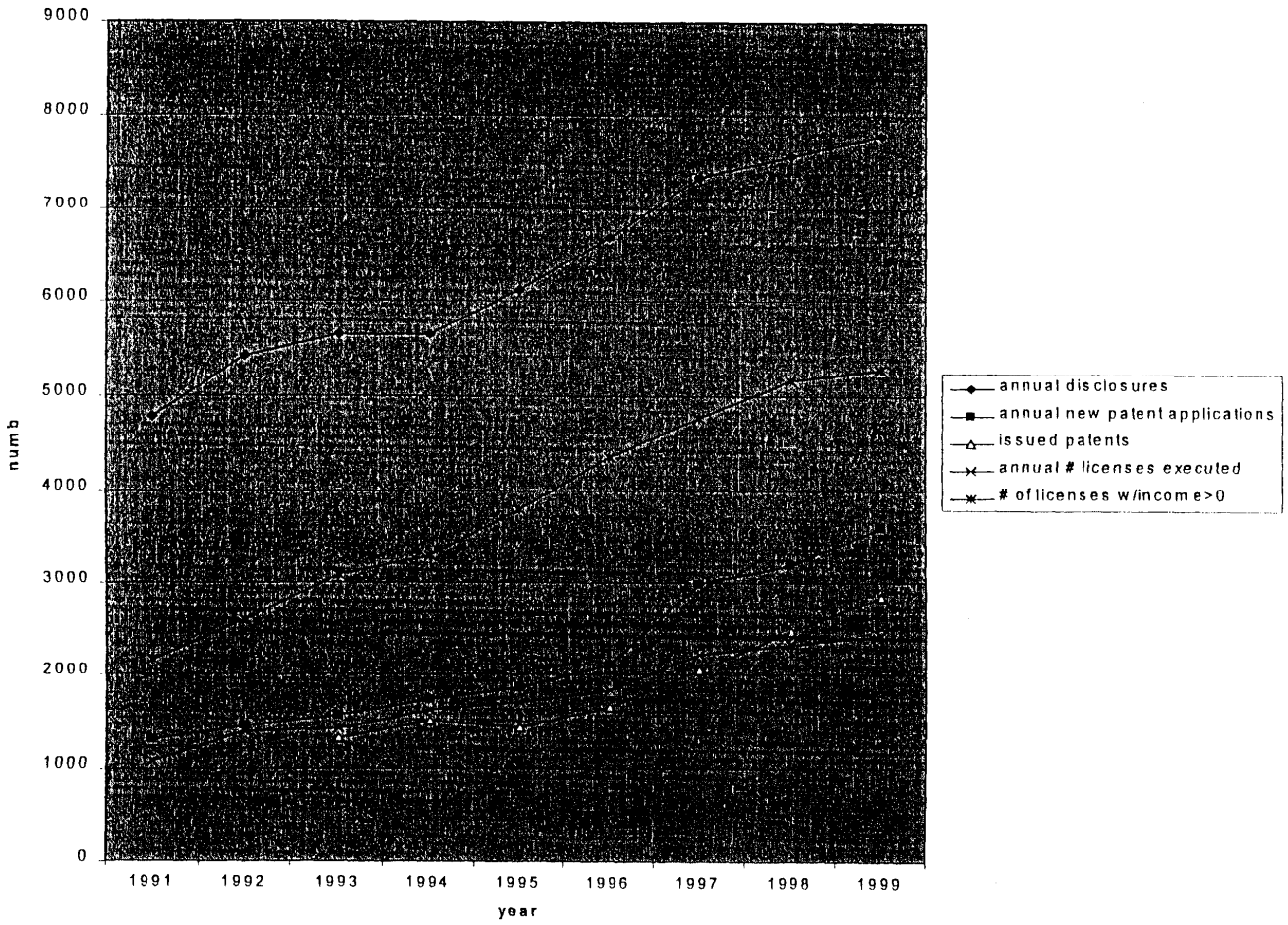
Entry by universities into patenting increases after Bayh-Dole

- "High-intensity" academic patenters (more than 10 patents assigned during 1970-80) account for 87% of academic patents in 1975, 64% in 1992.
- "Medium-intensity" academic patenters ($\leq$ 10 patents during 1970-80) account for 15% of academic patents in 1975, 30% in 1992.
- "Entrant" academic patenters (no patents during 1970-80) account for 0% of patents in 1975, 6% in 1992.

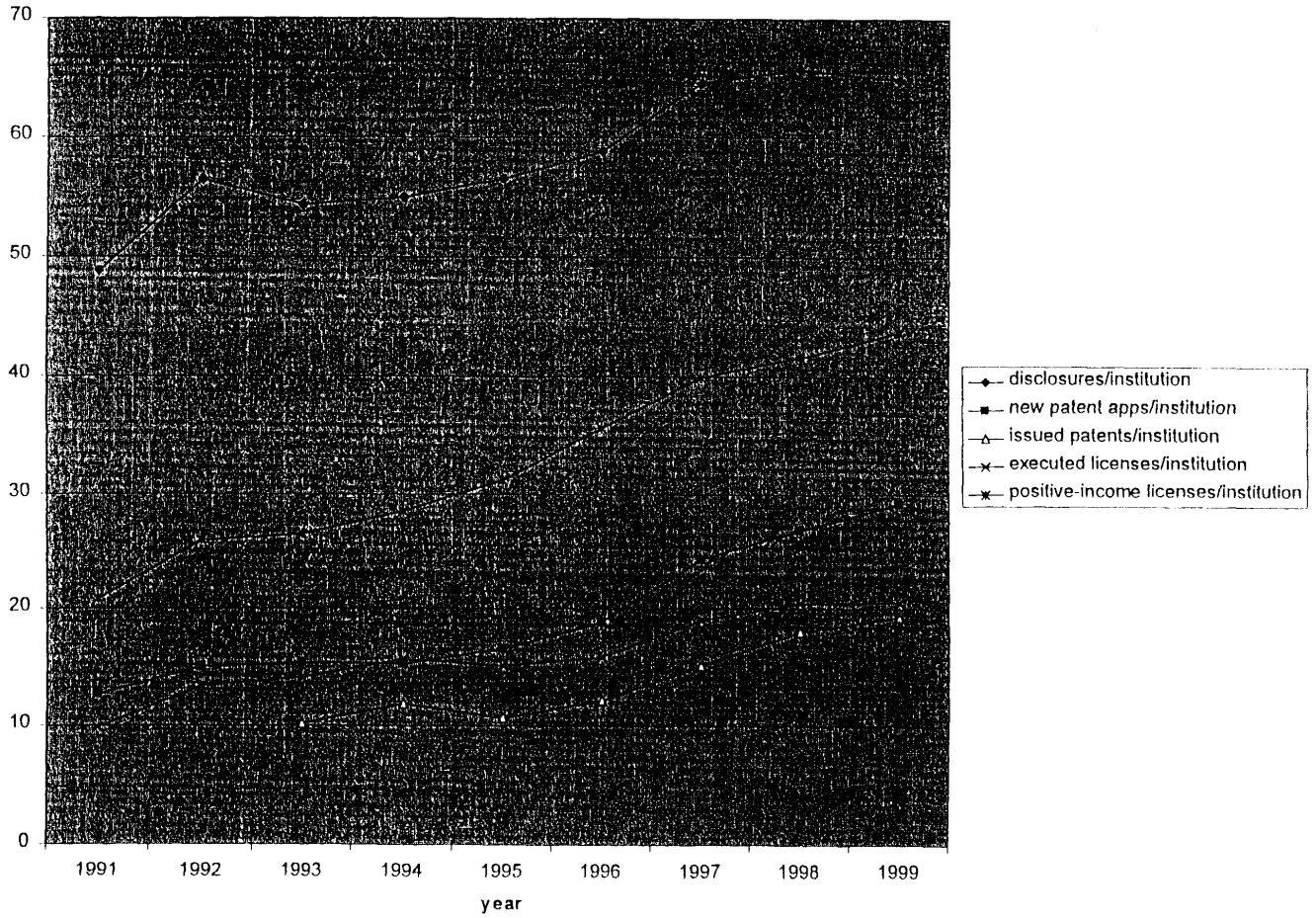
Aggregate trends in the 1990s

- Drawn from surveys conducted by the Association of University Technology Managers.
- Surveys report results separately for "recurrent" respondents and all respondents, enabling some control for entry.
- Little/no data on the distribution of revenues, costs, licenses among institutions.

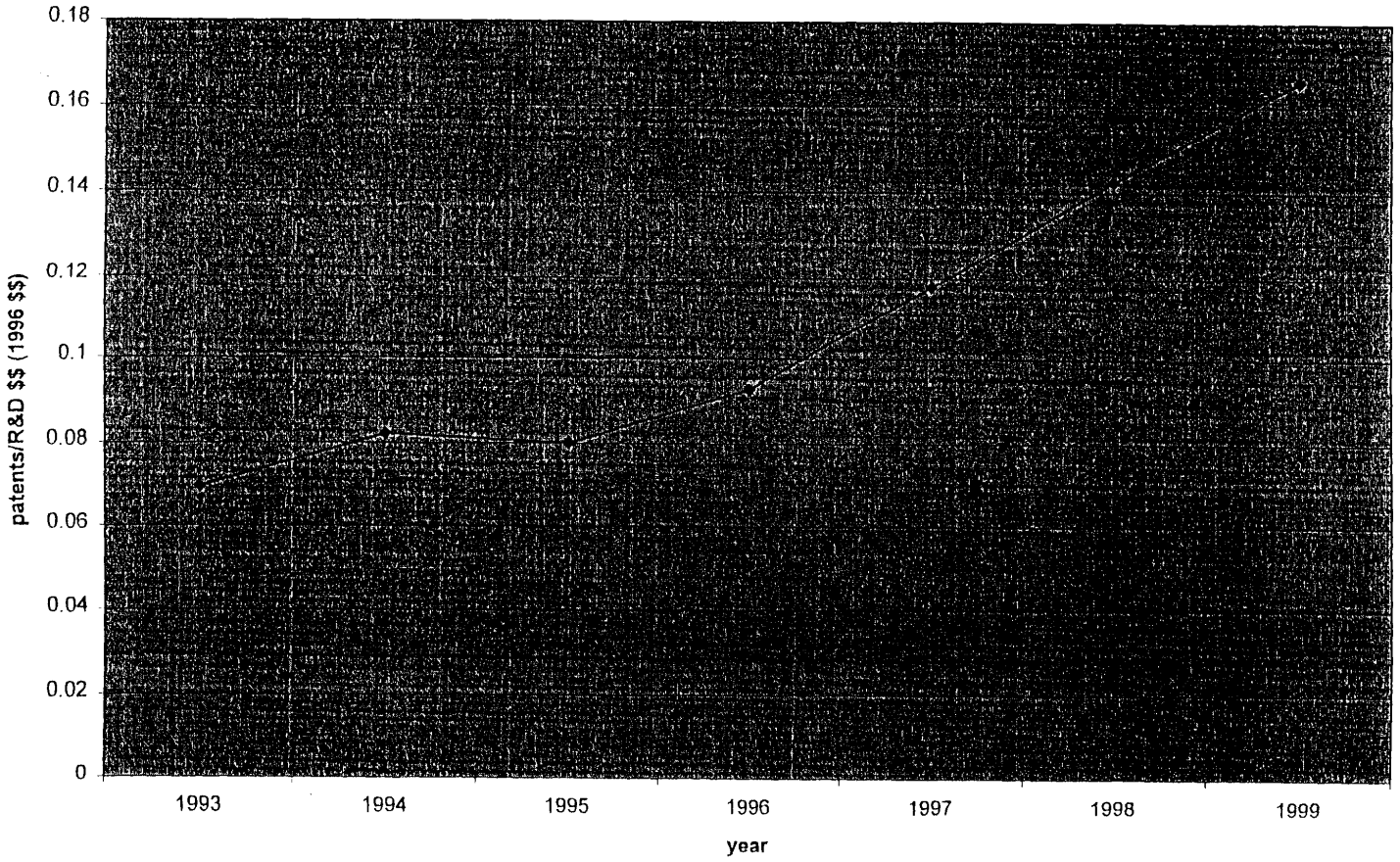
Trends in disclosures, patents, and licenses, AUTM "recurrent respondents," FY1990 - 98



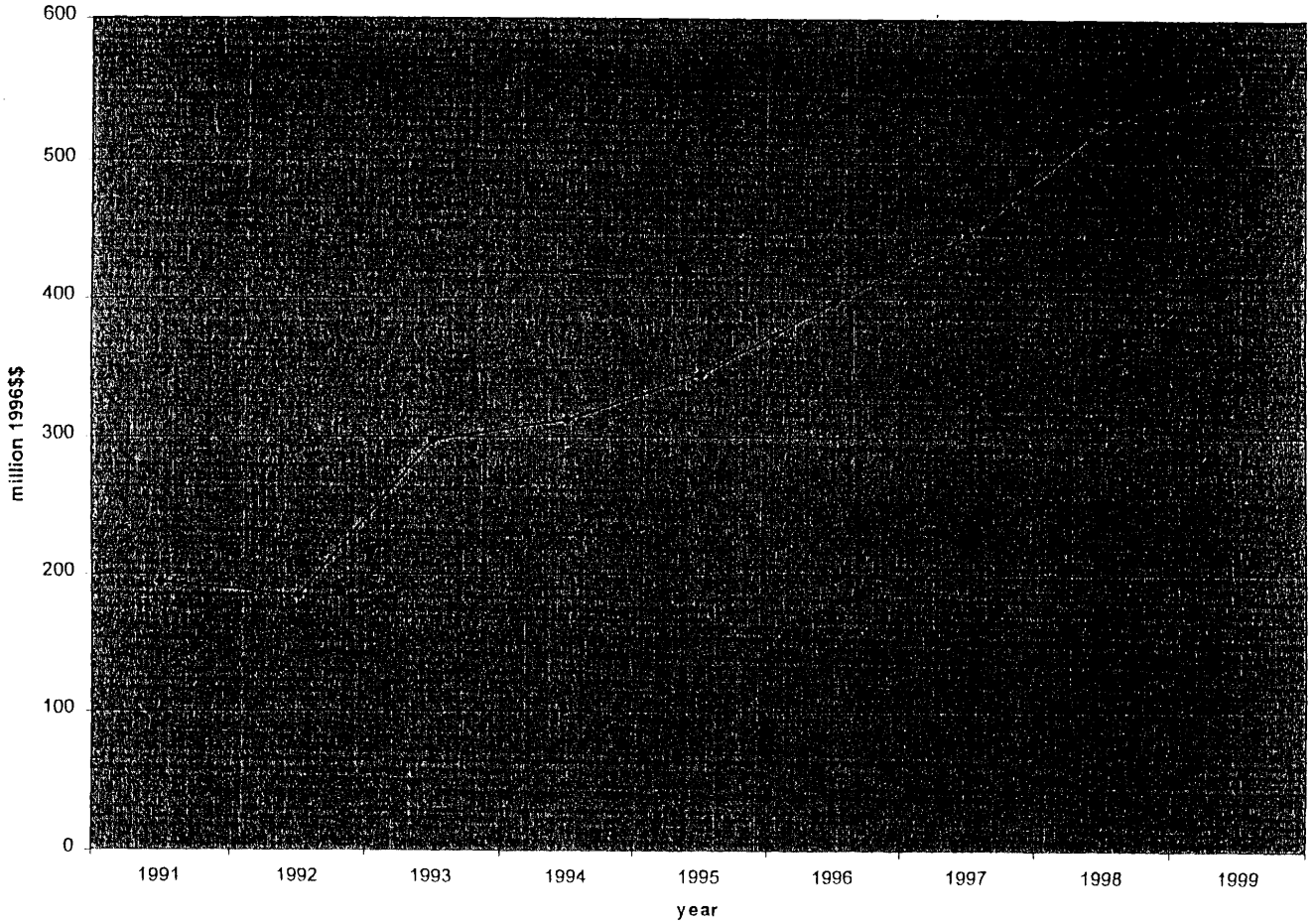
Per-institution trends in disclosures, patents, and licenses, all AUTM survey respondents, FY1990 -98



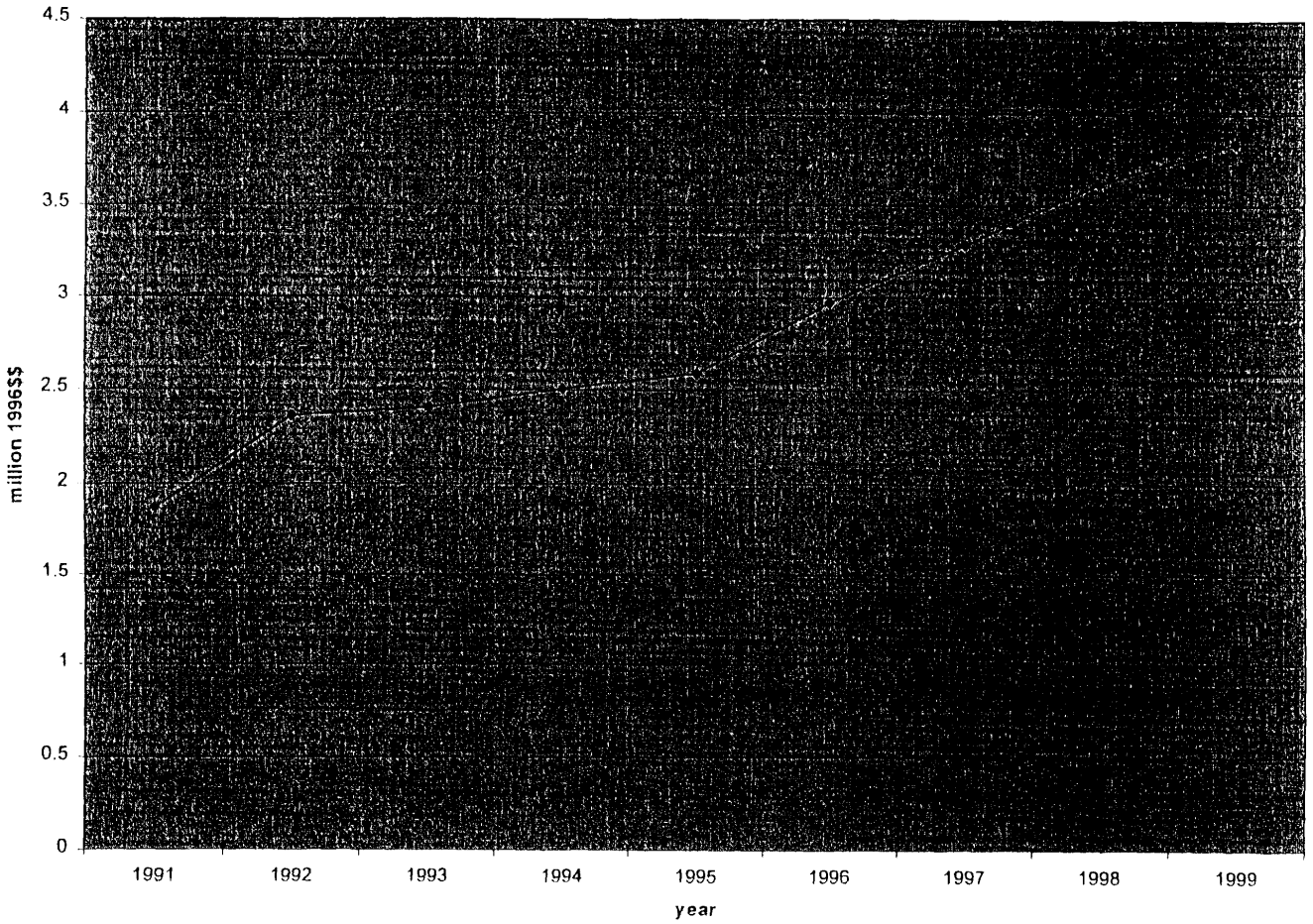
Patents/R&D expenditures, all AUTM respondents, FY 1993-99



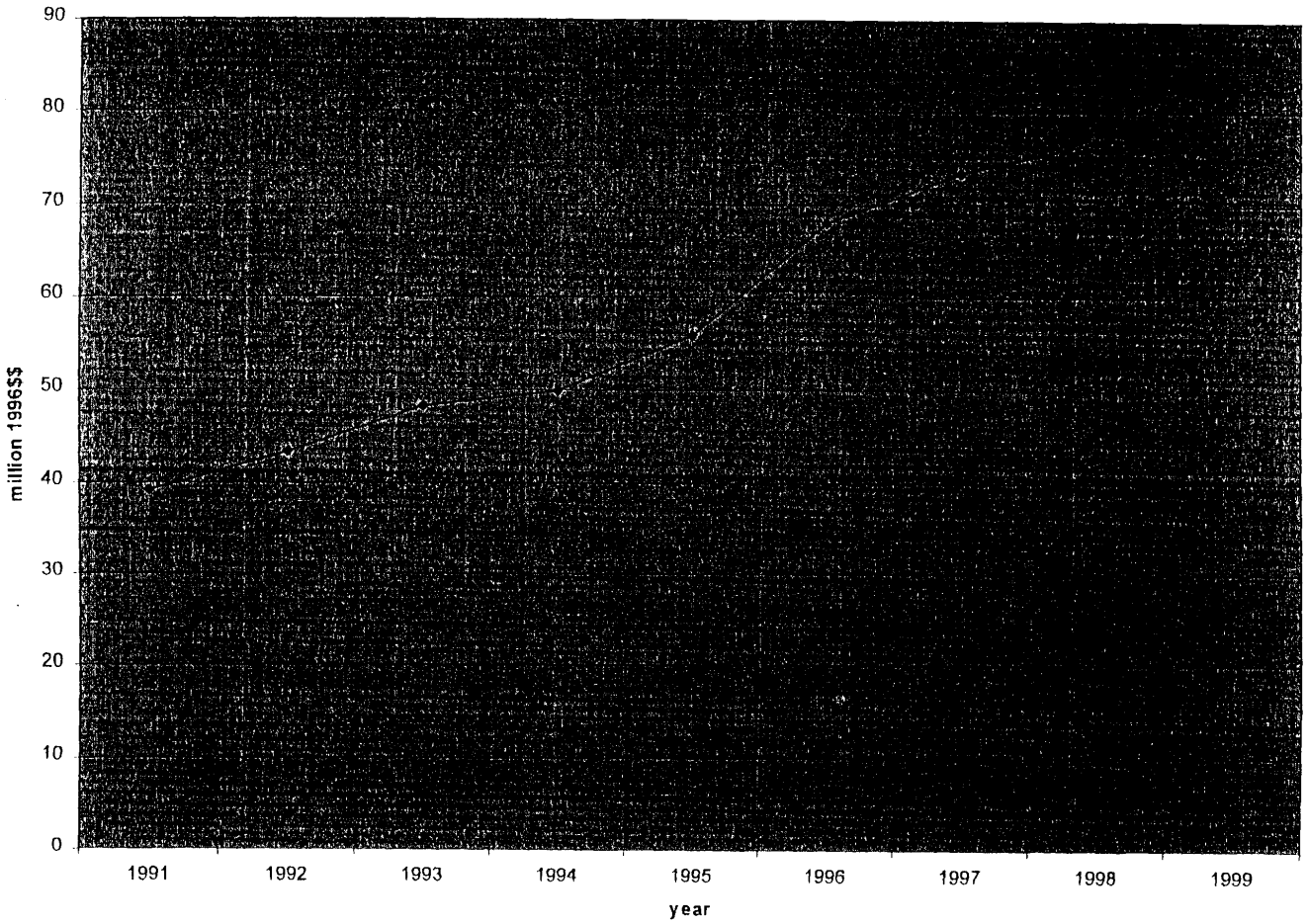
Gross licensing income, FY 1990-98, AUTM survey "recurrent respondents" (n=82)



Gross licensing income/institution, all respondents to AUTM survey, FY 1990-98



gross legal fees, FY 1990-98, AUTM "recurrent respondents" (n=73)



Unanswered questions and concerns

- What are the institutional objectives of university patenting and licensing?
  - Income generation from licensing fees/royalties.
  - Technology transfer for regional economic development.
  - Research fundraising.
  - How do universities manage conflicts among these objectives?
- What evidence do we have on the effectiveness of patents in supporting the transfer and commercial application of university technologies?
- How if at all has the growth of university patenting affected the "research culture" of leading US universities?

Unanswered questions and concerns (2)

- When is patenting a help and when is it a hindrance to university-industry research collaboration?
- How if at all should patenting policies be tailored to the different circumstances of different technology fields?
- Is dissemination of academic research results that formerly were published being limited by emphasis on patenting?
- What fraction of universities that seek to use technology transfer to generate income are successful in realizing significant net income?

附錄二

NATIONAL INSTITUTES OF HEALTH
OFFICE OF THE DIRECTOR

DETERMINATION
In the Case of
PETITION OF CELLPRO, INC.

The National Institutes of Health (NIH) has determined that the initiation of march-in procedures, as requested under the petition outlined below, is not warranted at this time. NIH retains jurisdiction over the instant proceedings until such time as a comparable alternative product becomes available for sale in the United States.

The CellPro Petition

On March 3, 1997, CellPro, Incorporated (CellPro) filed a petition with the Secretary of Health and Human Services (Secretary) requesting that the Government exercise march-in rights under the Bayh Dole Act (Act), 35 U.S.C. §§ 202-212, in connection with certain patents owned by The Johns Hopkins University (Hopkins) and licensed first to Becton-Dickinson and then to Baxter Healthcare Corporation (Baxter).[1] As discussed in greater detail below, the march-in provision of the Act authorizes the Government, in certain circumstances, to require the contractor (or grantee) or its exclusive licensee to license a Federally-funded invention to a responsible applicant on reasonable terms, or to grant such a license itself. CellPro asserts that such action is necessary to alleviate health or safety needs that have arisen because the United States District Court for the District of Delaware (Court) has found the stem cell separation device developed by CellPro, the Ceprate SC, to infringe two of the patents in question and has enjoined its sale.[2] Alternatively, CellPro asserts that march-in is warranted because Hopkins and Baxter have failed to take reasonable steps to commercialize the technology. At the present time, CellPro is the only company that has an FDA-approved device commercially available.

The Department of Commerce regulations implementing the Act are set forth at 37 CFR § 401.6. According to § 401.6(b):

> [w]henever an agency receives information that it believes might warrant the exercise of march-in rights, before initiating any march-in proceedings, it shall notify the contractor in writing of the information and request informal written or oral comments from the contractor, as well as information relevant to the matter.

The regulations provide that "the agency shall, within 60 days after it receives the comment, either initiate the procedures below or notify the contractor, in writing, that it will not pursue march-in rights on the basis of the available information." Id. Pursuant to § 401.6, the NIH, which has the delegated authority to make the march-in determination in this case, notified Hopkins of the petition and requested comment. Hopkins made its initial response on May 7, but in the interim, CellPro had made an additional submission to which Hopkins sought to respond. In sum, CellPro made supplemental filings on April 24, May 8, May 28 and July 2. After its initial response on May 7, Hopkins made supplemental filings on May 19, June 2 and July 2. Because the parties continued to make submissions and insist on the right to comment on the submissions of the other party, the NIH informed the parties that the 60 days set forth in the regulations for a determination by the agency would be calculated from June 2nd, but

agreed to review and consider any submissions made by the parties through July 2.[3]

The administrative record in this matter consists of the submissions of the parties, letters from universities, corporations, members of Congress, and other members of the public on this issue, as well as other pertinent materials obtained by the NIH.

Statutory Background and Criteria

The stated policy and objective of the Bayh-Dole Act is:

> to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

Act at § 200. Toward this goal, the Act addresses not only rules governing the licensing of Government-owned inventions, but also addresses Federal contractors'[4] rights to elect title to inventions made with Federal funding. In giving Federal contractors the right to elect title to inventions, Congress altered the preexisting scheme under which the funding agency generally owned patentable inventions made with Federal support unless the contractor obtained a waiver. Congress believed that this change would promote the utilization and commercialization of inventions and would harmonize Federal patent policies. See Senate Rep. No. 96-480 at p.3.

In giving contractors the right to elect title to inventions made with Federal funding, the Act also includes various safeguards on the public investment in the research. For example, the Federal agency retains a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world. See 35 U.S.C. § 202(c)(4). In addition, the Act includes march-in rights, which provide a Federal agency with the authority in certain, very limited circumstances, to make sure that a federally funded invention is available to the public. Section 203(1) states:

> With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such--

a. action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
b. action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
c. action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
d. action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.[5]

Jurisdiction

In its submissions, Hopkins suggested that NIH did not have jurisdiction in this matter. CellPro disagreed. It is our conclusion that NIH has jurisdiction to determine whether to exercise march-in with respect to the patents in question. The patents which were found by the Court to be valid and infringed are U.S. Patent Nos. 4,714,680 ('680 patent) and 4,965,204 ('204 patent). Documentation submitted by Hopkins clearly establishes that the inventions claimed in these patents were funded by the NIH. For instance, with regard to the '680 patent, Hopkins submitted to the NIH a letter dated October 4, 1984, notifying the NIH that Hopkins had elected title to the invention. In addition, Hopkins provided annual utilization reports filed during the 1980's and early 1990's, and a license from Hopkins to the U.S. Government, which expressly acknowledges that "the invention was made in the course of research supported by the DHHS."[6] Since the inventions were funded by the NIH, as acknowledged by Hopkins well before the patent dispute with CellPro arose, there is a clear presumption of jurisdiction by the NIH, and Hopkins has not submitted sufficient evidence to rebut that presumption.

Decision

The NIH has evaluated the administrative record with regard to two prongs of the statutory criteria, 35 U.S.C. § 203(1)(a) and (b). The NIH has examined whether, (1) Baxter has failed to take, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject inventions; and, (2) there exists a health or safety need which is not reasonably satisfied by Hopkins or Baxter.[7] Based on these criteria and the available information, march-in is not warranted at this time.

Practical Application of the Subject Inventions

Practical application is defined under 37 C.F.R. § 404.3(d) as "to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms." The administrative record demonstrates that Hopkins and Baxter have clearly met this standard.

This technology was originally developed in the laboratory of Dr. Curt Civin at Hopkins and first published in 1984. Hopkins filed for patent protection and was awarded four patents, the

first of which issued in 1987. The technology was first exclusively licensed to Becton-Dickinson & Co. (BD). BD began marketing the first anti-CD34 antibody in 1985 and has sold anti-CD34 antibodies worldwide ever since. Since BD was only interested in the diagnostic applications, the company exclusively sublicensed therapeutic rights to Baxter. Baxter began development of a therapeutic system and sublicensed rights to Applied Immune Sciences (now part of RPR Gencell) and Systemix (now part of Novartis). Baxter also held licensing discussions with CellPro, but no license agreement was signed.

By late 1991, Baxter had developed a prototype stem cell selection device. In 1992, Dr. Civin began clinical trials with the device, and Baxter started its own clinical trials in 1993. In January 1995, Baxter's Isolex 300 System received regulatory approval in Europe (CE Mark of Conformity for Medical Devices). In the United States, Baxter's systems have been installed in numerous transplant centers over the past three years; the Baxter device has been used in clinical trials to process peripheral blood and bone marrow for hematopoietic reconstitution in patients. On February 24, 1997, Baxter filed for Pre-market Approval (PMA) of its Isolex 300SA System.[8] In addition to effectively licensing and developing the technology, Hopkins, BD and Baxter have aggressively defended the patents in court. In 1994, the three parties joined in a suit against CellPro for infringement of the Civin patents.

Accordingly, NIH concludes that Hopkins and Baxter have taken effective steps to achieve practical application, as demonstrated by Hopkins' licensing, Baxter's manufacture, practice, and operation of the Isolex 300, and the device's availability to and use by the public to the extent permitted at this time under applicable law (i.e., foreign sales as well as widespread clinical research use in the U.S.). With regard to FDA approval and commercial sale of the Baxter Isolex 300 in the United States, the administrative record indicates that Baxter is vigorously pursuing an active application. Based on these facts, we conclude that Hopkins and Baxter have met the statutory and regulatory standard for practical application.

Health or Safety Needs

The question of whether the CellPro Ceprate SC fulfills health or safety needs not reasonably satisfied by the Baxter Isolex 300 has been the central inquiry and priority of the NIH in evaluating CellPro's petition for march-in. In this regard, we note the considerable debate among scientists and clinicians as to whether immunoselection of stem cells with selection devices prior to transplantation provides a clinically significant benefit to patients over standard hematopoietic transplantation techniques. The clinical benefit upon which the CellPro Ceprate SC device was approved by FDA consisted of a reduction of infusional toxicity associated with the administration of bone marrow prepared with standard techniques.[9] To date, neither party has presented to the Biological Response Modifiers Advisory Committee any studies documenting that cell separation devices improve stem cell engraftment, disease-free survival, or overall survival.[10] Thus, it is premature for either Baxter or CellPro to claim patient benefits (other than a decrease in infusional toxicities) from stem cell isolation and purification, T-cell, lymphocyte, and tumor cell purging, or other claimed uses.

It is equally premature, and inappropriate, for NIH to substitute its judgment for that of clinicians and patients seeking to avail themselves of an FDA-approved medical device. The FDA has determined that the Ceprate SC is safe and effective for selecting stem cells from autologous bone marrow for hematopoietic reconstitution. Thus, to the extent that the Ceprate SC is the only device that is available for sale in the United States for this purpose, it fulfills a

health need for those who wish to use it, until such time as a comparable alternative product becomes available for sale.[11]

As explained more fully below, the administrative record demonstrates that Hopkins and Baxter have taken appropriate steps to reasonably satisfy this need. First, they have refrained from enforcing patent rights to the full extent of the law in order to allow the continuing sale of the Ceprate SC until the Baxter product is approved for sale by the FDA. Second, they have pledged to ensure that the Baxter product is as widely available as possible through clinical trials, and to ensure patient access to the fullest extent possible.

(1) Continuing Sale of CellPro Device

In deference to the health need fulfilled by the CellPro device in the absence of an FDA-approved alternative, Hopkins and Baxter have refrained from enforcing their patent rights to the full extent of the law. Specifically, they modified a proposed order of injunction filed for consideration in the patent litigation in Federal District Court. The Order issued by the Court on July 24, 1997 states, in pertinent part:

> CellPro may continue to make, have made, use and sell SC Systems and disposable products (including the 12.8 antibody) for use with SC Systems, within the United States, until such time as an alternative stem cell concentration device, manufactured under a license under the >204 and >680 patents, is approved for therapeutic use in the United States by the United States Food and Drug Administration . . . and for a period of three months thereafter.

Order at p 5. In addition, certain price and volume restrictions contained in the Court's Order specifically do not apply to the provision of products solely for use in clinical trials. Order at pp. 5, 7.

CellPro argues vigorously, however, in documents filed prior to the entry of the Court's Order, that the terms of the proposed order, most specifically the requirement of payments to Baxter for sales of CellPro product, would force CellPro out of business and result in the loss of availability of the CellPro device.

First, we rely on the Court's finding that it is unlikely that the terms of the Order will result in the loss of availability of the CellPro product.[12] This issue was specifically before the Court, supported by an exhaustive factual record resulting from years of litigation. Although NIH is determining whether to open a fact-finding proceeding, as opposed to conducting one, we also found no convincing evidence that CellPro will be unable to supply patients with its product under the terms of the Court Order. The terms of the Order may be unpalatable to CellPro, but CellPro need only operate under those constraints pending a decision on its appeal of the Court's adverse verdict on infringement. The Court specifically found that CellPro "possesses adequate cash reserves to allow it to continue operations during the pendency of its appeal," Memorandum Opinion at p. 24, and determined that it would most likely be in CellPro's interest to continue operations pending the outcome of the appeal. Moreover, the Court has retained jurisdiction and invited the parties to apply to the Court for modification of the terms of the injunction, specifically, the payment of incremental profits to Baxter, if the amount determined by the Court "either provides inadequate relief or works an injustice inconsistent with equitable principles." Id.

Second, the loss of availability of the CellPro product is relevant to the "health need" criteria only during the period prior to FDA approval and availability for sale of a comparable alternative product. In petitioning NIH to open a separate proceeding on this matter, CellPro argues that its continuing viability and success, even beyond FDA approval of a comparable alternative, should be a matter of concern to the NIH because CellPro has developed and is marketing an important health care product. Invoking our prior caveat as to the investigational nature of these devices, we concur that, as a general matter, NIH supports the development and success of the biotechnology industry. It is indeed very important to the NIH that biotechnology and pharmaceutical companies thrive and compete in order to bring new health care products to the public. Developing and commercializing such products out of federally-funded research is the foundation and essence of the Bayh-Dole Act.

We are wary, however, of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies. The patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the development and dissemination of new and useful technologies. It has proven to be an effective means for the development of health care technologies. In exercising its authorities under the Bayh-Dole Act, NIH is mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research.

On balance, we believe it is inappropriate for the NIH to intercede in this matter to ensure CellPro's commercial future. Viability and success in the private sector is appropriately governed by the marketplace, and significantly influenced by management practices and decisions. CellPro had the opportunity to license the invention from Baxter but decided against doing so, and instead risked patent infringement litigation. It would be inappropriate for the NIH, a public health agency, to exercise its authorities under the Bayh-Dole Act to procure for CellPro more favorable commercial terms than it can otherwise obtain from the Court or from the patent owners. CellPro's commercial viability is best left to CellPro's management and the marketplace.

(2) Reasonable Steps to Ensure Widespread Availability of Baxter's Product

Hopkins and Baxter have also pledged to reasonably satisfy any health need created by the loss of the CellPro product in the unlikely event that patient access to this technology is restricted before a comparable alternative product is approved by the FDA and becomes available for sale.

In several of its submissions to NIH, and in a letter from Baxter CEO Vernon Loucks to Secretary Donna Shalala, Baxter committed to ensuring there would be no gap in patient access to stem cell separation technology. Baxter committed to installing its device free of charge at any site from which CellPro might withdraw, and to provide that site with the same level of support on the same terms as CellPro. Baxter also committed to obtaining all clinical and regulatory approvals necessary to place the Isolex system into operation as soon as possible.

CellPro asserted that Baxter is unable to fulfill this pledge; however, neither party submitted evidence sufficient for a definitive determination, and it would be premature for the NIH to act

based on Baxter's failure to accomplish what events have not yet required it to do. In any event, we believe the likelihood of Baxter having to substitute devices in order to ensure patient access is remote, as discussed above. Nevertheless, pending FDA approval and availability for sale of a comparable alternative product, NIH will continue to monitor the situation and will retain jurisdiction to initiate march-in without the filing of a new request, in the event that health needs are not being reasonably satisfied.

Conclusion

The NIH has determined not to initiate proceedings to pursue march-in rights on the basis of the available information. NIH has examined the criteria of 35 U.S.C. § 203(1)(a) and (b) and found that march-in is not warranted under either criteria. Specifically, the NIH has determined that Hopkins and Baxter have taken, or are expected to take within a reasonable time, effective steps to achieve practical application of the applicable patents, as demonstrated by Hopkins' licensing activities and Baxter's manufacture, practice, and operation of the Isolex 300, as well as the pending applications for FDA approval. NIH also finds that the available information fails to demonstrate an unmet health need that is not reasonably satisfied by Hopkins and Baxter.

The NIH will continue to monitor issues related to patient access to the CellPro or Baxter devices during the period prior to FDA approval and availability for sale of a comparable alternative device.

/s/

Harold Varmus, M.D.
Director, NIH

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[1] These patents are: U.S. Patent No. 4,965,680; U.S. Patent No. 5,130,144; U.S. Patent No. 5,035,994 and U.S. Patent No. 4,965,204.

[2] The Order for Permanent Injunction and Partial Stay of Injunction (Order), entered July 24, 1997, includes a partial stay allowing CellPro to continue selling its device under certain restrictions. CellPro has indicated that it intends to appeal the Court's ruling.

[3] Hopkins made an additional submission July 29, which was not considered by NIH.

[4] Defined in the Act as "any person, small business firm or nonprofit organization that is a party to a funding agreement," Act at § 201(c). In 1983, President Reagan issued a memorandum instructing all Federal agencies, to the extent not prohibited by law, to grant all recipients the same right to their inventions as the Bayh-Dole Act provided small businesses and nonprofit institutions.

[5] The legislative history to the Act indicates that Congress anticipated that third parties, such as CellPro in this case, would be likely to inform the Government of the possible need for march-in. However, it is clear that march-in remains a purely government authority. Senate Report

No. 96-480 states that:

> "[m]arch-in" is intended as a remedy to be invoked by the Government and a private cause of action is not created in competitors or other outside parties, although it is expected that in most cases complaints from third-parties will be the basis for the initiation of agency action.

[6] Although these documents relate specifically to the '680 patent, the '204 patent states that it is a divisional application of the application, serial number 670,740 (the '740 application), from which the '680 patent issued. The claims in the '204 patent are, therefore, based on the original disclosure that was contained in the '740 application, as to which Hopkins had elected title. The other two patents also involved in the patent litigation, U.S. Patent Nos. 5,035,994, and 5,130,144, also issued from divisional applications of the '740 application.

[7] The two other prongs are clearly not relevant. Subparagraph (c) narrowly applies to "public use" required by particular laws. CellPro has not claimed any such law to be applicable in the present case, nor does NIH believe any to be applicable. Subparagraph (d) authorizes march-in when an exclusive licensee of a subject invention has failed to agree (or obtain a waiver of such requirement) that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States. Baxter has agreed to manufacture substantially in the United States.

[8] CellPro has argued that the NIH should distinguish between the Isolex SA, an earlier, less automated device, and the Isolex 300i, Baxter's current fully-automated device. The current PMA application to FDA relates to the Isolex SA device. As is customary, the FDA recently discussed the Baxter PMA application for the 300SA device with the Biological Response Modifiers Advisory Committee (July 24, 1997). The majority of the committee members (13 out of 16) voted that the SA device yields an enriched cell population that produces successful engraftments. Thus, NIH finds that the Isolex SA and the 300i have comparable functions for the purpose of this determination.

[9] See, Transcript, FDA Biological Response Modifiers Advisory Committee meeting, February 28, 1996; Package Description, Ceprate SC Stem Cell Concentration System (December 6, 1996).

[10] Transcript, FDA Biological Response Modifiers Advisory Committee meeting, February 28, 1996. At that public meeting, Dr. Richard Champlin, MD Anderson Cancer Center, introducing the CellPro device on behalf of CellPro, stated to the Committee, "[a]gain, one has to remember this is not a treatment for cancer. This is a means to enrich stem cells for a variety of purposes. It has again been shown to be reproducible, safe, and effective for that purpose. And this technology is really critical to allow us to develop the field in a number of other very important applications." Transcript at pp. 21-22.

[11] The Baxter Isolex 300 constitutes such a comparable alternative product. Both the Isolex 300 and the Ceprate SC devices are used in clinical research to isolate and purify stem cells from either bone marrow or peripheral blood, in preparation for stem cell transplantation. Both are under investigation for either autologous (patient's own) or allogeneic (donor) transplantations. We find that performance differences alleged by both parties primarily affect

convenience of use, and do not alter the public health impact at issue here.

[12] According to the Court in its Memorandum Opinion at p. 23, "[a]fter evaluating the parties' arguments, and their accompanying declarations, the court finds that in the absence of a conclusive statement from CellPro executives that it will discontinue operations, it has failed to establish that a highly speculative risk of shutdown during the pendency of its appeal to the Federal Circuit outweighs the harm suffered by plaintiffs as the result of CellPro's willful infringement." Nonetheless, the Court modified one of the terms of the injunction, as proposed by Hopkins and Baxter, to require CellPro to pay 60 percent of its incremental profit from infringing sales, as opposed to the 100 percent proposed by Hopkins and Baxter.

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UNIVERSITY OF CALIFORNIA GUIDELINES ON MANAGING POTENTIAL CONFLICTS OF INTEREST IN LICENSING

(August 1, 2001)

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POLICY

President Saxon, in his June 23, 1980 memorandum to Chancellors and Laboratory Directors, stated that the University's overall policy on conflict of interest is that "none of its faculty, staff, managers, or officials shall engage in any activities which place them in a conflict of interest between their official activities and any other interest or obligation." Over the years a variety of specialized policies and guidelines have been issued in recognition of the need for further direction in this and in related areas of ethical standards and codes of conduct.

These guidelines are issued by the Office of Technology Transfer, UCOP at the request of Provost King and Senior Vice President Mullinix in their June 18, 2001 letter to Chancellors and Laboratory Directors in which they asked each site to implement the requirements of California's Political Reform Act with regard to licensing University research results. These guidelines address University decisions made in the course of licensing activities, and not matters of patent prosecution.

GUIDELINES

The Political Reform Act of 1974 ("Act") and its accompanying regulations set forth complex and comprehensive rules designed to assure that public officials "perform their duties in an impartial manner, free from bias caused by their own financial interests or the financial interests of persons who have supported them." The rules apply to public officials at all levels of government in California, from the Governor on down to city officials, and include University faculty and UC administrators. The Act creates the Fair Political Practices Commission ("FPPC") to interpret and enforce its provisions.

These guidelines address some of the most common concerns regarding potential conflicts of interest in University licensing activity, and shall be followed to implement the requirements of the Act. They are developed to clarify the roles of both inventors and licensing professionals and to assist them in complying with the Act. The guidelines also apply to authors whose works will be licensed by the University. For purposes of these guidelines and related documents, "inventors" is meant to include "authors" and "inventions" is meant to include "works of authorship", where applicable.

The conflict of interest coordinators at the Office of the President, the campuses, and the Laboratories; and attorneys at the Office of General Counsel will do their best to answer additional questions with respect to compliance with the Act and should be able to provide guidance about most common situations. The law and regulations are complex, however, and only the State Fair Political Practices Commission itself can offer a definitive interpretation of the Act.

I. University Licensing Decisions

Why does the University license inventions?

The University licenses its inventions to encourage the practical application of the results of research for the broad public benefit; to address the needs of sponsors of University research; to build research partnerships with industry to enhance the research and educational experience of researchers and students; and to generate royalty income for the further support of research and education; and to provide an incentive for inventor faculty retention and support of the University technology transfer program.

Who makes licensing decisions for the University?

Licensing Professionals (LP) within University authorized licensing offices (ALOs) are charged to license University inventions. They have the responsibility to make complex licensing decisions based upon a multiplicity of facts and circumstances by applying their professional expertise and experience.

LPs must conduct the technology transfer process, including patenting, marketing, and licensing in a manner that supports the principles of openness, objectivity and fairness in decision-making. University selection of licensees and other decisions made in the course of licensing University research results must be made in accordance with the Act, with University Licensing Guidelines (see OTT Guidance Memo No. 00-05, http://patron.ucop.edu/ottmemos/docs/ott00-05.html), and based upon the education, research, and public service missions of the University.

What is the role of inventors in making licensing decisions?

Licensing Professionals sometimes ask University inventors to work closely with University licensing staff and candidate licensees and even to involve themselves in companies that are candidate licensees to help effectively commercialize University inventions. This is appropriate and represents a useful contribution, because the transfer of University technology to industry is in the public interest and is consistent with the University's mission. Any involvement of inventors, however, must be in accordance with the Act, with University Licensing Guidelines (see OTT Guidance Memo No. 00-05, http://patron.ucop.edu/ottmemos/docs/ott00-05.html), and based upon the education, research, and public service missions of the University.

What does the Political Reform Act require regarding licensing decisions?

Because both Licensing Professionals and inventors may have the opportunity to influence University licensing decisions in ways that could lead to personal gain or give advantage to companies in which they have a financial interest, LPs and the inventors must be aware of and in

compliance with the Act. Generally, LPs and inventors are prohibited from "making, participating in making or influencing a University decision," including" including selection of licensees and other decisions made in the course of commercializing University research results, if they have a personal financial interest in the decision, unless certain specific actions are taken.

In order to comply with the Act, when a University employee has a personal financial interest in a decision concerning a candidate licensee of an invention, either

i. that employee must disqualify him or herself from "making, participating in making or influencing a University decision" concerning that invention, including selection of licensees and other decisions made in the course of commercializing the invention; or
ii. when that employee does not disqualify him or herself from involvement in such decisions, a Licensing Decision Review of the licensee selection and other licensing decisions must occur.

The Political Reform Act will permit participation in negotiating, advising or making recommendations with respect to any University decision, including those related to licensing, so long as there is appropriate review by non-interested persons or persons. The Act requires an intervening review--in other words, another level of review before the work product goes to the final decision-maker for approval. A Licensing Decision Review is a form of intervening substantive review as required by the Act. For further information about the Licensing Decision Review see "What is Licensing Decision Review?" below.

What exactly is a Disqualifying Personal Financial Interest?

The Political Reform Act states that a public official has a disqualifying personal financial interest in a decision if it is reasonably foreseeable that the decision will have a material financial effect, distinguishable from its effect on the public generally, on the University employee, a member of his or her family, or on any of the following:

i. Any business entity in which the public official has a direct or indirect investment worth $2,000 or more.
ii. Any real property in which the public official has a direct or indirect interest worth $2,000 or more.
iii. Any source of income, other than gifts and other than loans by a commercial lending institution in the regular of business on terms available to the public without regard to official status, aggregating $500 or more in value provided to, received by or promised to the public official within 12 months prior to the time when the decision is made.
iv. Any business entity in which the public official is a director, officer, partner, trustee, employee, or holds any position of management.
v. Any donor of, or any intermediary or agent for a donor of, a gift or gifts aggregating $320 or more in value provided to, received by, or promised to the public official within 12 months prior to the time when the decision is made.

In relation to i) and ii) above, a LP or inventor has an indirect investment or interest if the investment or interest is owned by his/her spouse or dependent child, by an agent on his/her behalf, or by a business entity or trust in which he/she, his/her agents, spouse, and dependent children own a 10 percent or greater interest.

Membership on a scientific advisory committee is not in itself a disqualifying personal interest as defined in (iv) above. However, any payment for serving on the advisory board, including

reimbursement for travel, accommodations or food, is potentially a disqualifying personal interest as defined in (iii) or (v) above.

The inventor's share of royalty income paid to a University inventor by the University relating to the licensing of his or her invention is not considered to be a disqualifying personal interest of the inventor in the licensee of that invention.

What is a Personal Financial Effect?

Financial effects on a University employee or a member of his or her immediate family are called "personal financial effects." Personal financial effects are considered a sixth form of disqualifying personal financial interest. Thus, a public official has a disqualifying personal financial interest in his or her current and *future* personal finances and those of his or her immediate family. A government decision will have an effect on this interest if the decision will result in the personal expenses, income, assets, or liabilities of the official or his or her immediate family increasing or decreasing. A *reasonably foreseeable* financial effect on a public official's personal finances is considered material under the Act if it is at least $250 in *any* 12-month period. For example, an employee may intend to start a company in order to commercialize his or her invention but perhaps does not currently have an interest in the company simply because it has not yet been established. Nevertheless, under the Act the employee could not participate in any way in University decisions related to licensing this invention because the official has a disqualifying personal financial interest in his or her own future personal finances (unless there is intervening substantive review - see Section III below).

When does a Licensing Professional or inventor "make" a University licensing decision?

Under the Act, a University employee "makes" a decision when, acting within the authority of his or her office, that employee votes on a matter, appoints a person, obligates or commits the University to any course of action, or enters into any contract on behalf of the University. It is important to recognize that a decision can also be made when one determines not to act, unless the determination not to act is the choice of disqualification (see Section II below). Thus a LP, for example, cannot proceed to make a decision even if that LP excludes from consideration as a potential licensee a serious candidate in which he or she has a disqualifying personal financial interest.

When does a Licensing Professional or inventor "participate" in the making of a University licensing decision?

An inventor or Licensing Professional participates in making a University decision when, acting within the authority of his or her position, he or she negotiates regarding the decision; or when the inventor or LP advises or makes recommendations to the University decision maker, by conducting research or making any investigation which requires the exercise of judgment on the individual's part and the purpose of which is to influence the decision; or when the inventor, for example, prepares or presents any report, analysis or opinion to University employees which requires the exercise of judgment and the purpose of which is to influence the University decision. Additionally, it is important to understand that a University employee does not "participate" in a University decision when he or she interacts with external decision-makers, for example, scientists or officials of candidate licensees.

When does a Licensing Professional or inventor attempt to use his or her official position to influence a University licensing decision?

An inventor or Licensing Professional attempts to use his or her official position to influence a University decision if, for the purpose of influencing the decision, that person contacts, appears before, or otherwise attempts to influence any officer, employee, or consultant of the University. This includes a situation where the inventor negotiates "across the table" from the University on behalf of a company in which he or she has a disqualifying personal financial interest. One mayAn inventor may, however, communicate with the general public or the press without violating this provision. An individual also is not "attempting to influence" a decision when the contribution to the decision-making process is only technical or "ministerial" as explained below. Additionally, it is important to understand that a University employee does not "participate" in a University decision when he or she interacts with external decision-makers, for example, scientists or officials of candidate licensees.

Are there certain technical advisory actions that are not considered to be "participating in the making of or influencing a decision"?

Some Licensing Professional or inventor contributions to the licensing process are primarily technical advice and do not constitute "participation in" or "attempting to influence" a governmental decision under the Act. They are called "ministerial." An action is ministerial, even if it requires considerable expertise and professional skill, if there is no discretion with respect to the outcome. Thus an inventor can provide technical or scientific *information* about an invention where necessary without being considered to be participating in a government decision. This exception, however, does not apply to technical tasks such as most data gathering or analysis in which the employee makes professional judgments which can affect the ultimate decision in question.

II. Self-Disqualification Under the Act

When is disqualification required as a result of a personal financial interest?

An inventor or Licensing Professional may not "make, participate in making, or in any way attempt to use [his or her] official position to influence" a University decision which will foreseeably have a material financial effect on the inventor or LP, on a member of that person's immediate family, or on the source of that interest (for example, a candidate licensee). The inventor or LP is disqualified for a period of 12 months following any point in time in which the interest exists, unless there is Licensing Decision Review.

What is the obligation under the Act of a University official with a financial interest?

If a Licensing Professionals or inventor determines that he or she has a disqualifying personal financial interest, that person may disqualify him or herself from making a University decision, and must refrain from participating in any way in the decision, and must not use his or her official position to influence any other University employees with respect to the matter. The determination not to act may be accompanied by disclosure of the disqualifying interest, but disclosure is not required.

***When and* how does a Licensing Professional disqualify him or herself from involvement in licensing decisions?**

The LP should formally disqualify him or herself by notifying his or her supervisor that he or she has a disqualifying personal interest in the licensing decision, and that he or she formally disqualifies him or herself from case management responsibilities.

When and how does an inventor disqualify him or herself from involvement in licensing decisions?

The inventor may disqualify him or herself by formally asserting in writing that he or she will not (as long as a disqualifying personal financial interest exists) make, participate in making, or attempt to influence a University licensing decision concerning the invention, including the selection of a licensee(s), and other decisions made in the course of attempting to commercialize the invention. Alternatively, the inventor may choose simple and absolute nonparticipation in all licensing decisions, even without formal written self-disqualification. This is sufficient to remain in compliance with the Act. Any such self-disqualification action should be taken in close coordination with the LP.

Whether or not the inventor has a disqualifying personal financial interest is important as early as the time the invention disclosure form (the Record of Invention or ROI) is completed. If the inventor has a disqualifying personal financial interest in a candidate licensee for the invention that is disclosed, he or she should make the self-disqualification decision when disclosure of the invention is made. If, on the other hand, the inventor with such an interest chooses *not* to disqualify him or herself, that inventor should preferably disclose the financial interest at this time--and certainly prior to the signing of any Secrecy Agreement with a candidate licensee. (See "When and how does an inventor disclose his or her financial interest in a candidate licensee?" below).

Who manages the invention after disqualification?

When a Licensing Professional disqualifies him or herself from management of an invention, the case would then be assigned by the LP's supervisor for management to another LP without a disqualifying personal financial interest in the decision.

When an inventor disqualifies him or herself from involvement in licensing decisions, any scientific or other advice determined necessary by the LP would be obtained from other co-inventors if available, other University scientists, or other sources with appropriate expertise.

III. Inventor Involvement in Licensing Decisions

Is there any way in which an inventor can remain involved in licensing decision-making?

When an inventor has a disqualifying personal financial interest, it is sometimes determined useful or necessary by the Licensing Professional for the inventor to be involved in the licensing decision-making process as his or her expertise and input may be important to successful licensing and technology transfer. In such cases, the LP may determine that it is beneficial for the

inventor--despite the existence of an interest--to work closely with the LP and with potential licensees, or to be directly involved with companies that are potential licensees. An inventor sometimes becomes involved by negotiating "across the table" from the University on behalf of a company in which the inventor has a disqualifying personal financial interest.

The Office of General Counsel has determined that the Political Reform Act will permit participation by an inventor, even where that inventor has a disqualifying personal financial interest, in advising, influencing, or making recommendations with respect to a University licensing decision, *so long as there is appropriate intervening substantive review,* called a Licensing Decision Review. Thus, when an inventor with a disqualifying personal financial interest in a potential licensee, is invited by the LP to participate in licensing decisions, and does not disqualify him or herself from participation, Licensing Decision Review of the licensee selection and other licensing decisions is required under the Act. Both the LP and the inventor must be agreeable to any inventor involvement, understanding that the extent to which the inventor participates in or influences licensing decisions may be a factor in the considerations and ultimate recommendations of the Licensing Decision Review body.

In general, the role of the inventor in licensing decisions should be kept to the minimum necessary to successfully achieve the University's objectives in licensing University research results for the public benefit.

When and how does an inventor disclose his or her financial interest in a candidate licensee?

When an inventor with a disqualifying personal financial interest in a candidate licensee has not and will not be "making, participating in making or influencing" a licensing decision, no financial disclosure is required. When an inventor *without* such a financial interest makes, participates in making or influences a licensing decision, again, no disclosure is required. If, however, an inventor who will be participating in the licensing decision-making activity has a disqualifying personal financial interest in any candidate licensee identified by the LP, that inventor is required under the Act to disclose his or her interest. Form TT-100, Inventor Statement Concerning Involvement in Licensing Decisions, must be used for this purpose. When such a financial interest is disclosed in such a circumstance, a Licensing Decision Review of LP-proposed licensing decisions is required. A Form TT-100 must be completed by the inventor, indicating whether or not he or she has any financial interest, for each company for which there is a Secrecy Agreement.

Inventor disclosure of financial interest on Form TT-100 should be made promptly upon request by the Licensing Professional. In most cases, this would be upon identification by the LP of candidate licensees and prior to the signing of any Secrecy Agreement. If no Form TT-100 is completed by the inventor, and if the inventor has been or will be involved in the licensing decision, the LP may determine that a Licensing Decision Review is appropriate.

What is Licensing Decision Review?

Licensing Decision Review means there is another level of review by a non-interested person or persons before a proposed licensing decision goes to the final decision maker for approval. The review must be based on an independent consideration and assessment of the facts of the case. The Licensing Decision Review body, composed of qualified staff with appropriate expertise, knowledge and professional judgment, must independently check the original data and analysis upon which the LP-proposed selection of licensees and other licensing decisions were made and

make its independent recommendations concerning the decisions.

Who conducts the Licensing Decision Review?

Each UC campus and Laboratory was directed in a June 18, 2001 letter to Chancellors and Laboratory Directors from Provost King and Senior Vice President Mullinix to establish a plan for conducting intervening substantive review of licensing decisions (in this case, called Licensing Decision Reviews), whether those licensing decisions are made in the systemwide Office of Technology Transfer (OTT) or at a campus or Laboratory Authorized Licensing Office. Each local Licensing Decision Review plan, including the processes, mechanisms and bodies (individuals or committees) established to carry out Licensing Decision Reviews may accommodate local needs and circumstances, but must be responsive to the direction provided in that letter and, consistent with these Guidelines, and must be filed with the OTT.

How does this Licensing Decision Review relate to Independent Substantive Review Committee (ISRC) reviews of financial interest in private sponsors of research?

In those cases where the Licensing Professional determines that a condition of a license agreement will require the licensee's support of additional research by the University involving the inventor with the disqualifying personal financial interest, the LP must inform the appropriate University Contract and Grant Officer that disclosure and review of financial interests under the University of California Policy on Disclosure of Financial Interest in Private Sponsors of Research is required.

Disclosure would be made on UC Form 730U and any required independent substantive review would be conducted by the local Independent Substantive Review Committee (ISRC) prior to execution of the license agreement requiring future research funding. Any required intervening substantive reviews of the licensing decision should be coordinated or combined with the ISRC review as appropriate. If it is not possible to secure approval by the ISRC of the proposed additional research prior to the execution of the license agreement, any license agreement requirement that the licensee support additional research involving the inventor with the disqualifying personal financial interest, could be made conditional upon the ISRC's future approval of such research by incorporating an appropriate "escape" provision in the license agreement in the event that the ISRC does not approve such research.