FORM CD-183
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FORMERLY SEC-35

U.S. DEPARTMENT OF COMMERCE

ABSTRACT OF SECRETARIAL CORRESPONDENCE

NOV 25 REC'D

TO:				
	X	The Secretary		The Deputy Secretary

Date: NOV 21 1986

FILE

DECISION MEMORANDUM

From: Under Secretary for Economic Affairs

Prepared by: Norman J. Latker/EA/OPTI/377-0659

SUBJECT: Implementation of the Federal Technology Transfer Act

STATEMENT OF THE ISSUE

What steps should the Department take to implement the Federal Technology Transfer Act of 1986?

ANALYSIS

On October 20, the President signed the Federal Technology Transfer Act of 1986 (P.L. 99-502), which amends the Stevenson-Wydler Act (P. L. 96-480). Commerce supported this Act as priority legislation. It builds on fundamental principles the Department developed for managing technology produced with Federal funding. The principles, which we have embodied in two previous laws and the President's Patent Policy Memorandum, give universities and businesses control of their technology and strong incentives to promote its commercial application. This Act finally extends these principles to Government-operated laboratories and, if implemented properly, can give U.S. industry practical access to nearly all unclassified technology the Government funds or produces in the laboratories.

Among the amendments are provisions that promote technology transfers by permitting agencies to authorize Government-operated laboratories to enter into cooperative research and development arrangements or licensing agreements with the private sector, subject to statutory or agency imposed conditions. The amendments also provide needed incentives

Control No. 625079

NBS EA 12/5 | PTO DQ 12/8 | Malcolm Baldrige DEC 10 1986

	PREPARED BY	CLEARED BY	CLEARED BY	CLEARED BY	CLEARED BY	CLEARED BY
SURNAME AND ORGANIZATION (Typed)	DBMerrifield A/S, PTI	RELlert Ch.C/EA	ES	Admin		ITA
INITIALS AND DATE	w/ltr pc	11/17	PC 12/9	KB 12/3	RHB 11/26	9 mF 12/8

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to encourage laboratories and their scientists to examine how the results of projects funded to meet Federal needs might be adapted to commercial uses. It does this by permitting the laboratories to accept resources from the private sector under cooperative arrangements and by assuring laboratory scientists a percentage of the royalties resulting from their inventions.

From its beginning, the Administration has been striving to increase American innovation by decentralizing the management of technology coming out of Federally supported programs. The Administration's policy is widely supported in the private sector. It is viewed by state and local governments as a centerpiece of local economic development. In order to take full advantage of this unique opportunity to broaden the U. S. technology base, the department must now move forcefully to implement the President's policy.

Within the Department of Commerce the technology transfer function contained in this new Act are the programmatic responsibility of the Under Secretary for Economic Affairs. Accordingly, as a first step in implementing the Technology Transfer Act of 1986, the additional agency level and Government-wide coordinating authorities vested in you by these new amendments to the Stevenson-Wydler Act should be delegated to the Under Secretary for Economic Affairs.

When this delegation has been made, we will create a DoC committee to implement the Technology Transfer Act of 1986, of all interested Departmental units in order to expedite implementation within the Department. The committee would undertake as a primary task the further delegation of the cooperative arrangement and licensing authorities to Commerce laboratories under appropriate conditions.

RECOMMENDATIONS

1. I recommend that you delegate the authorities and responsibilities given you under these new amendments to the Stevenson-Wydler Act to the Under Secretary for Economic Affairs. (Attached at tab A is a summary of the authorities to be delegated to the Under Secretary for Economic Affairs. Also attached at tab B is a copy of Public Law 99-502, with the new authorities to be delegated underlined in red). If you agree with this proposed delegation, we will coordinate with the Assistant Secretary for Administration to amend the appropriate Departmental Orders.

DECISION

Approve ✓ Disapprove_____ Let's Discuss_____

DEC 10 1986

2. I recommend your approval of the establishment by the Under Secretary for Economic Affairs of a DoC committee to implement the Technology Transfer Act of 1986.

DECISION

Approve ✓ Disapprove _____ Let's Discuss _____

DEC 10 1986

COORDINATING AUTHORITIES CREATED BY P. L. 99-502

I. Government-wide Coordinating Authority Assigned to the Commerce Department by P. L. 99-502

Section 10(g)(1)

The Secretary, in consultation with other Federal agencies, may--

(A) make available to interested agencies the expertise of the Department of Commerce regarding the commercical potential of inventions and methods and options for commercialization which are available to the Federal laboratories, including research and development limited partnerships;

(B) develop and disseminate to appropriate agency and laboratory personnel model provisions for use on a voluntary basis in cooperative research and development arrangements; and

(C) furnish advice and assistance, upon request, to Federal agencies concerning their cooperative research and development programs and projects.

Section 10(g)(2)

Two years after the date of the enactment of this subsection and every two years thereafter, the Secretary shall submit a summary report to the President and the Congress on the use by the agencies and the Secretary of the authorities specified in the Act...

Section 10(g)(3)

Not later than one year after the date of the enactment of the Federal Technology Transfer Act of 1986, the Secretary shall submit to the President and the Congress a report regarding--

(A) any copyright provisions or other types of barriers which tend to restrict or limit the transfer of federally funded computer software to the private sector and to State and local governments, and agencies of such State and local governments; and

(B) the feasibility and cost of compiling and maintaining a current and comprehensive inventory of all federally funded training software.

II. Agency-level Coordinating Activities Created by P. L. 99-502

A. Cooperative Agreements

Section 11(a)

Each Federal agency may permit the director of any of its Government-operated Federal laboratories--

(1) to enter into cooperative research and development agreements on behalf of such agency (subject to subsection (c) of this section)..., and

(2) to negotiate licensing agreements...

Section 11(c)(1)

A federal agency may issue regulations on suitable procedures for implementing the provisions of this section...

Section 11(c)(3)(A)

Any agency using the authority given it under subsection (a) shall review employee standards of conduct for resolving potential conflicts of interest...

Section 11(c)(3)(B)

If...an agency is unable to resolve potential conflicts of interest within its current statutory framework, it shall propose necessary statutory changes to be forwarded to its authorizing committees in Congress.

Section 11(c)(5)(A)

If the head of the agency...desires an opportunity to disapprove or require the modification of any such agreement, the agreement shall provide a 30-day period within which such action must be taken beginning on the date the agreement is presented to him or her by the head of the laboratory concerned.

Section 11(c)(5)(B)

In any case in which the head of an agency... disapproves or requires the modification of an agreement..., the head of the agency...shall transmit a written explanation of such disapproval or modification to the head of the laboratory concerned.

B. Awards Program

Section 12

The head of each Federal agency that is making expenditures at a rate of more than $50,000,000 per fiscal year for research and development in its Government-operated laboratories shall...develop and implement a cash awards program to reward its scientific, engineering, and technical personnel for--

(1) inventions, innovations, or other outstanding scientific or technological contributions of value to the United States due to commercial applications or due to contributions to missions of the Federal agency or the Federal Government, or

(2) exemplary activities that promote the domestic transfer of science and technology development within the Federal Government and result in utilization of such science and technology by American industry or business, universities, State or local governments, or other non-Federal parties.

C. Distribution of Royalty Income

Section 13(a)(1)

Except as provided in paragraphs (2) and (4), any royalties...received by a Federal agency from the licensing or assignment of inventions...shall be disposed of as follows:

(A)(i) The head of the agency...shall pay at least 15 percent of the royalties...to the inventor....This clause shall take effect on the date of the enactment of this section unless the agency publishes a notice in the Federal Register within 90 days of such date indicating its election to file a Notice of Proposed Rulemaking pursuant to clause (ii).

(A)(ii) An agency may promulgate... regulations providing for an alternative program for sharing royalties with inventors...

Section 13(a)(1)(A)(iii)

Any agency that has published its intention to promulgate regulations under clause (ii) may elect not to pay inventors under clause (i) until the expiration of two years after the date of the enactment of this Act or until the date of the promulgation of such regulations, whichever is earlier. If an agency makes such an election and after two years the regulations have not been promulgated, the agency shall make payments (in accordance with clause (i)) of at least 15 percent of the royalties involved, retroactive to the date of the enactment of this Act. If promulgation of the regulations occurs within two years after the date of the enactment of this Act, payments shall be made in accordance with such regulations, retroactive to the date of the enactment of this Act. The agency shall retain its royalties until the inventor's portion is paid under either clause (i) or (ii)...

Section 13(a)(1)(B)

The balance of the royalties...shall be transferred by the agency to its Government-operated laboratories, with the majority share of the royalties... going to the laboratory where the invention occurred...

Section 13(a)(2)

If, after payments to inventors under paragraph (1), the royalties received by an agency in any fiscal year exceed 5 percent of the budget of the Government-operated laboratories of the agency for that year, 75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent may be used or obligated for the purposes described in...paragraph (1)(B) during that fiscal year or the succeeding fiscal year. Any funds not so used or obligated shall be paid into the Treasury of the United States.

Section 13(a)(4)

A Federal agency receiving royalties...as a result of invention management services performed for another Federal agency or laboratory...shall retain such royalties...to the extent required to offset the payment of royalties to inventors under...paragraph 1(A), costs and expenses incurred under clause (i) of paragraph (1)(B), and the cost of foreign patenting....All royalties...remaining after payment of... royalties, costs, and expenses... shall be transferred to the agency for which the services were performed...

D. Record Keeping

Section 11(c)(6)

Each agency shall maintain a record of all agreements entered into under this section.

Section 13(c)(1)

In making their annual budget submissions Federal agencies shall submit...summaries of the amount of royalties...received and expenditures made... under this section.

E. Federal Laboratory Consortium

Section 10(e)(1)

There is hereby established the Federal Laboratory Consortium for Technology Transfer...which, in cooperation with Federal laboratories and the private sector, shall--

(E) utilize...the expertise and services of...the Department of Commerce...,as necessary.

Section 10(e)(2)

...The representatives to the Consortium shall include...a representative appointed from each Federal agency with one or more member laboratories.

Section 10(e)(7)(C)

The heads of Federal agencies...may provide such additional support for operations of the Consortium as they deem appropriate.

TRANSMITTAL 011

United States of America DEPARTMENT OF COMMERCE	DEPARTMENT ORGANIZATION ORDER 10-9 Amendment 1	
DEPARTMENT ORGANIZATION ORDER SERIES	DATE OF ISSUANCE March 9, 1987	EFFECTIVE DATE March 5, 1987

SUBJECT

UNDER SECRETARY FOR ECONOMIC AFFAIRS

Department Organization Order 10-9, dated January 22, 1984, is hereby amended as shown below. The purpose of this amendment is to delegate the Secretary's authority in the Federal Technology Transfer Act of 1986; and transfer previously delegated authorities in the Stevenson-Wydler Technology Innovation Act of 1980 from the Assistant Secretary for Productivity, Technology and Innovation to the Under Secretary for Economic Affairs.

SECTION 3. DELEGATION OF AUTHORITY. In pen-and-ink, reletter paragraphs .02 through .04 as .03 through .05, a new paragraph .02 is added to read as follows:

".02 The authorities and responsibilities of the Secretary of Commerce in the Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480), as amended by the Federal Technology Transfer Act of 1986 (P.L. 99-502)."

Secretary of Commerce

USCOMM- DC - 87-8951

OFFICE OF FEDERAL TECHNOLOGY COMMERCIALIZATION

SECTION 1. PURPOSE

.01 This Order prescribes the organization and the functions of the Office of Federal Technology Commercialization.

SECTION 2. STATUS AND LINE OF AUTHORITY

.01 The Office of Federal Technology Commercialization, a constituent operating unit of the Department, shall be headed by a Director who shall report and abe responsible to the Under Secretary for Economic Affairs through the Assistant Secretary for Productivity, Technology and Innovation.

SECTION 3. FUNCTIONS

The Office of Federal Technology Commercialization shall be the principal unit in the Department on issues and policies relating to technology developed in Federal laboratories, developed with Federal funding, or affected by Federal programs and activities. In carrying out these responsibilities, the Office shall:

a. Advise the Under Secretary for Economic Affairs and other Department officials on important policy questions and problems relating to private sector use of Federal technology.

b. Enhance the flow of Federally funded technologies to the private sector and minimize adverse affects of Federal programs on technology developed by the private sector.

c. Assist the Under Secretary for Economic Affairs in performing the lead agency functions delegated by the Secretary, concerning Federal technology management policy under Public Laws 96-480, 96-517, 98-620, 98-622, and 99-502 and Executive Order 10096 and the President's patent policy memorandum, including coordinating, monitoring, gathering relevant data, evaluating relevant programs and activities, developing uniform Government-wide standards for implementing Federal patent policy, preparing reports, disseminating information, making recommendations, and taking other actions necessary to assure maximum private sector opportunity for commercializing technology resulting from projects performed by Federal agencies or financed with Federal Government funds.

d. Review for the Under Secretary and advise on, all Commerce activities under the Stevenson-Wydler Technology Transfer Act of 1980 and the Federal Technology Transfer Act of 1986.

e. Chair the Federal Coordinating Council on Science, Engineering, and Technology Committee on Intellectual Property for Technology Transfer.

f. Develop a Government-wide policy on technical data used or developed at Government expense.

g. Develop training materials and programs for helping Federal laboratories or Federally-funded laboratories evaluate the commercial value of their technologies and improve their technology transfer capabilities.

h. License Federally-owned inventions both within the custody of the Department of Commerce and other agencies.

i. Chair the Commerce Committee on Laboratory Technology Management, to coordinate implementation of authority delegations to DOC laboratories under subsection 11(a); the awards program authorized by section 12 of P.L. 99-502 and the distribution of royalties under Section 13 of P.L. 99-502.

j. Prepare the reports from the Secretary to the President and Congress as required in P.L. 99-502.

SECTION 4. ORGANIZATION

.01 The Office of Federal Technology Commercialization shall consist of the Division of Federal Technology Management Policy and the Division of Federal Patent Licensing.

02. The Division of Federal Technology Management Policy shall:

a. Provide advice and assistance as requested by other Federal agencies on commercializing inventions, model agreements, and cooperative research and development projects as authorized by paragraph 10(g)(1) of P.L. 99-502.

b. Develop the biennial report required by subparagraph 10(g)(2) of P.L. 99-502 to the President and Congress on Government-wide use of the authorities provided in the Act.

c. Analyze and propose new legislation or other policies including Government-wide regulations on management of technology developed by the Government or with Government funding, including preparation of the report to Congress and the President required by paragraph 10(g)(3) of P.L. 99-502.

d. Draft Commerce regulations as may be necessary to comply with subsection 11(c) of P.L. 99-502.

e. Develop and administer policies for distributing royalty income within the Department of Commerce in accordance with subsection 13(a) of P.L. 99-502.

f. Issue, interpret, and maintain regulations under P.L. 96-517 and 98-620 on ownership of Government funded inventions (37 CFR Part 401) and licensing of Government-owned inventions (37 CFR Ch.IV).

g. Interpret and administer Government Employee Inventor Program under E.O. 10096, including recommendations for changing the Order if necessary to conform with new legislation.

h. Work with agencies to help take advantage of the Statutory Invention Recording process authorized by P.L. 98-622 and develop the required annual report.

i. Provide advice and assistance to the Director of the Office of Science and Technology Policy on matters related to managing technology developed by the Government or with Federal funding.

03. The Division of Federal Patent Licensing shall:

a. Negotiate agreements with Federal laboratories and/or agencies for provision of services related to licensing of laboratory or employee inventions.

b. Provide services to Federal laboratories and/or agencies in finding potential licensees, negotiating licenses, and administering licenses including collecting royalty payments.

c. At laboratory and/or agency request, file patent applications, particularly for overseas patents.

d. Provide training on a reimbursable basis to Federal agency and laboratory personnel in patent licensing.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

	Inventor	University	Invention	Licensee	Approximate Investment
1.	Walser	Johns Hopkins U.	Keto-Acid analogs of Amino Acids for treatment of uremia	Pfrimmer of Germany and Syntex of U.S.A	Millions - Clinical trials in process. Expected to be marketed in 6 mos. in Europe.
2.	Wiktor	Wistar Institute	Rabies Vaccine	Wyeth Laboratories	On the market - millions
3.	Kamen et al	Case Western Res.	Methotrexate Assay during Cancer Chemotherapy	Diamond Shamrock Corp.	Being test-marketed. Production scheduled for late 1977. Millions.
4.	Lillehei/Kaster	U. of Minnesota	Pivoting Disc Heart Valve	Medical, Inc.	Being sold in world-wide market since 1971. Millions.
5.	Blackshear et al	U. of Minnesota	Implantable Infusion Pump (Constant Infusion of Drugs for Treatment of Cancer, Diabetes, Pain, Morphine-addiction, etc.)	Metal Bellows Co.	Undergoing clinical trials. $750,000.
6.	DeLuca	U. of Wisconsin	25-Hydroxycholecalciferol for treatment of Osteo-dystrophy with liver dysfunction	Rousel-Uclaf (Hoechst) and Upjohn	Have applied for equivalent of NDA in France. Approximately $5 million. About to apply for an NDA and an NADA. Will spend about $10 million.
7.	DeLuca	U. of Wisconsin	1-Alpha Hydroxycholecalciferol for treatment of Osteo-dystrophy with Kidney Dysfunction	Leo Pharma-ceuticals	Applying for new drug applications in Denmark and Great Britain. May be marketed this year. Approx. $5,000,000.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

	Inventor	University	Invention	Licensee	Approximate Investment
8.	DeLuca et al	U. of Wisconsin	1, 25-Dehydroxyergocalciferol for Treatment of Osteodystrophy with Kidney and Liver Dysfunction and Senile Osteodystrophy	Hoffman-LaRoche Inc.	About to apply for NDA. Will spend about $10 million.
9.	Fox	Columbia U.	Silver Sulfadiazine used in Treatment of Burns	Marion Labs., Kansas City, Mo.	Now on market - Approx. $5,000,000
10.	Heidelberger	U. of Wisconsin	Use of F_3TDR for Herpes Infections of the Eye	Burroughs Wellcome Co., Research Triangle Park, N.C.	Approx. $5,000,000 NDA expected by end of 1977.
11.	Fischell	Johns Hopkins U.	Rechargeable Cardiac Pacemaker	Pacesetter Systems Sylmar, California.	On market since Feb. 1975 - Approx. $720,000
12.	Holland	Tulane U.	Method of Reducing Intraocular Pressure in the Human Eyes (Glaucoma Treatment)	Cooper Labs., Bedford Hills, N.Y.	$2,000,000 - Development leading to NDA is in process and on schedule
13.	Pressman	U. of Miami	Application of X-537A in the Cardiovascular System (for stimulation in cardiogenic shock, congestive heart failure, etc.)	Hoffman-LaRoche, Nutley, N.J.	$500,000 to $1,000,000 Clinical evaluations still in progress
14.	Higley	Natl. Institute of Scientific Research	Polycarbonate Dialysis Membranes (kidney dialysis)	C. R. Bard Inc., Murray Hill, N.J.	Over $1,000,000. Market introduction expected imminently.
15.	Talbot/Harrison	Johns Hopkins U.	Ballistocardiograph Apparatus	Royal Medical Corp. Huntsville, Ala.	Approx. $330,000. Now on market.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

	Inventor	University	Invention	Licensee	Approximate Investment
16.	Plotkin	Wistar Institute	Rubella Vaccine	1) Wellcome Foundation 2) L'Institut Merieux 3) Swiss Serum and Vaccine Institute and others (Merck, an Italian firm, etc.)	Approx. millions - Now on market.
17.	Schaffner/Mechlinski	Rutgers U.	Derivatives of Polyene Macrolide Antibiotics	E.R. Squibb of U. S. A. and Dumex of Denmark	Millions - Clinical trials progressing favorably
18.	Zweig	Syracuse U.	Apparatus for Measuring and Controlling Cell Population Density in a Liquid Medium	New Brunswick Scientific Co., Inc., of New Jersy	Millions - On the market since 1973
19.	Lovelock	Yale U.	Gas Analysis Method and Device for the Qualitative and Quantitative Analysis of Classes of Organic Vapors	Varian Associates, Palo Alto, Calif.	On the market
20.	Fried	U. of Chicago	Prostoglandins for possible Treatment of Bronchial Asthma, Duodenal Ulcers, Inflammatory Conditions, etc.	Richardson-Merrell, New York, N.Y.	Several millions - In process of development and testing for marketing here and abroad
21.	Leininger/Grotta et al	Battelle Memorial Institute	Preparation of Non-thrombogenic Surfaces and Materials	C. R. Bard, Inc., Billerica, Mass.; Sherwood Medical Industries, St. Louis Mo.; and American Hospital Supply Corp., Irvine, California.	$107,754 - Some products being marketed and others being tested.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

Inventor	University	Invention	Licensee	Approximate Investment
22. Merrifield	Rockefeller U.	Apparatus for the Automated Synthesis of Peptides	Beckman Instruments, Fullerton, California	Being marketed since 1973.
23. Smith/Kozoman	Duke U.	Apparatus and Method for Rapid Harvesting of Roller Culture Supernatant Fluid	Bellco Glass, Inc. Vineland, New Jersey	$25,000 - Being marketed since June 9, 1976
24. Zweng	Stanford U.	Laser Photocoagulator	Coherent Radiation, Palo Alto, Cal.	Approximately $500,000 Standard tool of ophtholmologists
25. Sweet et al	Stanford U.	Cell Sorter	Becton-Dickinson, Rutherford, New Jersey	Approx. $200,000. Importa research tool
26. Boyd/Macovski	Stanford U.	Computerized Axial Tomography	S.A.I. Cupertino, Cal.	Approx. $300,000. Will be marketed soon.
27. Saxena	Cornell U.	Method for Testing for Pregnancy	Carter-Wallace	Approx. 1/2 million On market
28. Calnek/Hitchner	Cornell U.	Cell-free virus Preparation	Merck	
29. Carlson	Iowa State	Respiratory Augmentor with Electronic Monitor and Control	Bourns, Inc.	On market since 1966; sales now in millions
30. Leake/Rappoport	Harbor General Hospital	Bone Induction in an Alloplastic Tray	Am. Hospital Supply	Data not available

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

	Inventor	University	Invention	Licensee	State of Development
31.	Bradford/ Williams	U. of Georgia	Protein Assay Reagent and Method	Bio-Rad Labs, Inc; Quantimetrix Corp.	On the market since April 1977
32.	Tenckhoff	U. of Washington	Catheter Insertion Trocar	Sweden Freezer Mfg. Co; Cobe Labs; Physio-Control Corp;	On market
33.	Leonard et al	U. of Illinois	Fluorescent Derivatives of Cytosine-Containing Compounds	PL Biochemicals	On market
34.	Secrist et al	U. of Illinois	Fluorescent Derivatives of Adenine-Containing Compounds	PL Biochemicals	On market
35.	Asgar	U. of Michigan	Partial Denture Alloy		On market
36.	Carlson/Ward	U. of Washington	Coherent Biological Cell Analyzer	3M Company	Marketing development in progress.
37.	Charlson/ Alhquist	U. of Washington	Integrating Nephelometer and Photon-Counting Integrating Nephelometer	Battelle Development	On market
38.	Thomas	U. of Washington	Artery-Vein Shunt Applique	Battelle Development Corp.	Being marketed

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

	Inventor	University	Invention	Licensee	State of Development
9.	Holcomb	Yale University	Method and Apparatus for Stimulation of Body Tissue	Avery Labs, Inc.	On the market since 1973
10.	Dugan	Temple University	Novel Compositions for Radiotracer Localization of Deep Vein Thrombi	Rand Research & Development Corp.	Licensed in 1977.
11.	Roelofs	Cornell University	Codling Moth Pheromone	Zoecon Corp.	On market since 1972.
12.	Whitby	Univ. of Minnesota	Particle Counter	Name not available	On market since 1969
13.	Bacaner	Univ. of Minnesota	Method for Suppressing Ventricular Fibrillation	Burroughs Wellcome	On market
44.	Whitby	Univ. of Minnesota	Aerosol Sampler	Not available	On market since 1969
45.	Bradley	Univ. of Minnesota	Apparatus to Stimulate the Bladder	Two licenses, names not available	On market since 1972
46.	BUTLER	Purdue Research Fdn.	Hydrophobic Noncovalent Binding of Proteins to Support Materials	Regis Chemical	On market since April 1977

	Inventor	University	Invention	Licensee	State of Development
47.	Rosenberg	Michigan State Univ.	Platinum Compounds as Anti-Tumor Agents	Possibly Adria, Bristol or Miles Labs.	On market in late 1977
48.	Coller	Institute for Cancer Research	Process of Viral Diagnosis and Reagent (Radioimmuno-assay)	Abbot Labs.	Licensed in 1977 (Canada) On market in U.S.A.
49.	Kosikowski	Cornell University	Antibiotic Test Kit	Bacto Strip	On market
50.	Kosikowski	Cornell University	Process for Milk Sterilization	De Laval Alpha Laval	On market
51.	McLafferty	Cornell University	Pregnancy Test	Carter-Wallace	On market
52.	Kattwinkel et al	Case Western Reserve	Device for Administering Pressure via Nasal Route	Sherwood Medical	On market since 1975
53.	Neckers et al	(Univ. of New Mexico (Wayne State University	Polymer-based Photosensitizers	National Patent Development Corp.	Being sold for research purposes only at this time
54.	Keith/Snipes	Penn. State Univ.	BHT Antiviral Agent	Key Pharmaceuticals	Development is at the IND stage
55.	Najjar	Tufts University	Therapeutically Useful Polypeptides	Calbiochem	Being sold for research purposes only at this time
56.	Story et al	Univ. of Georgia	Macrocyclic Compounds	(Chemical Samples Company (Albany International	Commercial marketing expected within the year
57.	Mielke	Institutes of Medical Sciences	Template for Ivy Bleeding Time	Hemakit, Inc.	Being sold commercially

	Inventor	University	Invention	Licensee	State of Development
58.	Murray/Somerset	State Univ. of N.Y.	Knee Joint Prosthesis	Howmedica, Inc.	On commercial market since 1976
59.	Volz/Brownlee/Tyers	Penn. State Univ.	Rechargeable Cardiac Pacemaker	Intermedics, Inc.	Near market
60.	Volz et al	Penn. State Univ.	Rechargeable Cardiac Pacemaker	Intermedics, Inc.	Being sold commercially
61.	Travis/Pannell	Univ. of Georgia	Albumin Recovery Method	Calbiochem	Research quantities of albumin isolated by this method being sold to investigators.
62.	Schaffner et al	Rutgers	Derivatives of Polyene Macrolide Antibiotics	E. R. Squibb	Nearing commercial market
63.	Kupchan et al	Univ. of Virginia	Ansa Macrolide Tumor Inhibitor	Bristol-Myers	In clinical development
64.	Peterson	North Star Res. (Midwest Res.)	Blood Compatible Polymers for Blood Exygenation Devices	Celanese Corp.	Development progressing to overcome serious barriers
65.	Juni	Univ. of Michigan	Test Kit for the Genetic Detection of Microorganisms	Miles Labs	In process of development.
66.	Schreiner	Univ. of Michigan	Pitch Synchronous Speech Band-with Compressor	Intermedics, Inc.	In process of development
67.	Craig	Univ. of Michigan	Hydrophobic Polymer Composite Restorative	Dentsply, Intl	In process of development
68.	Phillips et al	Colorado State	Therapy for Calf Diarrhea	Norden Labs.	NDA under review
69.	Parlow	Harbor General Hospital	Male Contraception Method	Sandoz, Inc.	In process of development
70.	Brooker et al	Univ. of Virginia	Complete Automation of Radioimmunoassay	Squibb & Sons	To be marketed in 1979
71.	Stoner et al	Univ. of Virginia	A Material for Binding Amalgam to Teeth	Star Dental Co.	Under development

Ohio's Economy Is Doing Fine.

Ohio is going to be a hard fought over state in this presidential election. And consequently, the economy of this bellwether state has become highly scrutinized.

But much of this scrutiny has focused only on the admittedly tragic loss of manufacturing jobs, while overlooking major investments in tax reform, technology and higher education. Things in Ohio are not as the news coverage has made them appear.

CROSS COUNTRY
By Ted Strickland And Lee Fisher

There's no question we face serious economic challenges, and that the national economy's decline has hit citizens hard in the wallet.

But the state has too many strengths, too many successes, and too noble a history to be portrayed as a poster child for the country's economic woes. Look under Ohio's hood. Its engine is being redesigned and retooled in ways that offer important lesson on how to make an economy more competitive in a global marketplace.

The biggest shift is in taxes. Ohio business leaders told us that our tax structure was outdated and made the state uncompetitive. So, in a bipartisan manner, we restructured our tax laws to lower the burden for business.

By 2010, Ohio will be one of only two states *without* a general tax on corporation profits or a property tax on business machinery, equipment and inventories. This year is the last for Ohio's business property tax; next year is the last for the corporation profits tax. And Ohio's personal income tax rates are falling by 21% across the board.

> We're cutting taxes to promote growth.

Between 2005 and 2007, Ohio's per capita state tax burden has already fallen to 38th in the nation, from 27th, according to the Federation for Tax Administrators. When the new tax cuts are phased in, Ohio's business taxes will be the lowest in the Midwest.

Exports, meanwhile, are booming. In 2007, Buckeye State exports totaled more than $42 billion, up 11.1% from 2006, making Ohio the only state in which exports have increased each year since 1998.

The labor force has experienced a dramatic shift in recent decades. There has been a loss of 254,000 manufacturing jobs over the decade ending in 2007. But there has also been an increase of 262,700 professional, health and education jobs over the same period.

Consider just one example. The Ohio State University Medical Center created 3,742 new jobs between 2001 and 2007 by targeting research grants related to cancer studies. Industry models show that $100 in research expenditures creates $222 in wealth in the local economy.

Research-generated jobs, however, require different skills than many in our manufacturing workforce have to offer. So we are investing the money needed to help workers gain the skills they need.

We've combined higher education and economic development funds to create a $150 million Ohio Research Scholars program, which will bring 26 world-class scholars to state campuses, individuals whose research specialties align with our economic development priorities. This investment builds on many others. The state has created a $1.6 billion Ohio Third Frontier program that invests in high-tech, advanced materials, bioscience, advanced energy and aerospace industries. The state is spending $250 million in a higher education internship program, and freezing tuition for two years for undergraduates so that more students can afford to stay in college. We're also spending $100 million in scholarships for students studying science, technology, engineering and math.

Ohio recently passed a bipartisan $1.57 billion jobs stimulus plan that will invest strategically in our infrastructure, future work force and growth industries such as biosciences and renewable energy. Our new Advanced Energy Portfolio Standard requires at least 25% of electricity sold in Ohio to be generated from new and advanced technologies by 2025. This will create vast new opportunities for green energy businesses in Ohio.

Already, Ohio has more alternative energy-related projects under way than any other state. The state's extensive manufacturing supply chain provides thousands of products to the alternative energy industry. And Ohio is home to the largest fuel cell supply chain in the country. Our welders, machinists, electricians, iron and steel workers are retooling and transferring their skills to retrofitting buildings, building mass transit, installing wind and solar power, and manufacturing energy-efficient cars and trucks.

Ohio now leads the Midwest in the growth of venture capital investments in the biosciences; we rank first nationally in per capita clinical trials and operate the largest center for stem cell and regenerative medicine between the coasts. In the U.S. News & World Report rankings, Ohio leads the nation with four of the country's top 15 children's hospitals. The Cleveland Clinic meanwhile has spun off two dozen start-up companies in the past decade, and averages 200 inventions each year.

Companies are responding to our business-friendly environment. Ohio ranked number one in both 2006 and 2007 in major new and existing business facilities expansion, according to Site Selection magazine.

Despite the portrait some paint of Ohio, we believe our greatest opportunities for economic growth still lie before us. And in our future, from tires to polymers, from auto glass to solar panels, from steel bars to wind turbines, Ohio will show that it reinvented itself.

Mr. Strickland, a Democrat, is governor of Ohio. Mr. Fisher, a Democrat, is lieutenant governor of Ohio.

Associated Press

Dana Corporation's automotive parts manufacturing plant in Lima, Ohio.

Practice tips for filing a Design Patent Application

By

James Gandy

Design Patent Practice Specialist

Practice Tip

Only claim what applicant created as their ornamental design

- Don't claim functional features unrelated to the design.

- Don't claim hidden structure or surfaces which form no part of the design.

Claim

Since the claim in a design patent application is directed to the **ornamental appearance** for an article, it follows that the visual disclosure is the most important part of the application.

Visual Disclosure

The visual disclosure must satisfy the requirements of 35 U.S.C. 112, first and second paragraphs.

That is, the shape and appearance of the claimed design must be shown in such full, clear, concise and exact terms as to enable a designer skilled in the art to which it pertains to reproduce it; and must particularly point out and distinctly illustrate the subject matter which applicant regards as their design invention.

Visual Disclosure

A poor quality visual disclosure could be fatal to obtaining design patent protection.

Pitfall – Filing Informal Drawings

Filing of informal drawings that have light, pale lines that do not permit an understanding of all surfaces and details of the design will result in a rejection of the claim under 35 U.S.C. 112. Such a rejection may not be able to be overcome without introducing prohibited new matter. 35 U.S.C. 132; 37 CFR 1.121(f).

Pitfall – Filing Photographs

Photographs must be of sufficient quality so that all details shown therein are reproducible in the printed patent, 37 CFR 1.84(b)(1).

Shadows and solid black areas in photographs may prevent a clear and adequate understanding of the design claimed which may result in a rejection of the claim under 35 U.S.C. 112. Such a rejection may not be able to be overcome without introducing prohibited new matter. 35 U.S.C. 132; 37 CFR 1.121(f).

Pitfall – Filing Photographs

Photographs to be accepted as formal drawings must be limited to the design claimed and must not disclose environmental structure, 37 CFR 1.152.

The above requirement limits the scope of the claimed design by showing all surfaces and details of the article including those portions that may be dictated by function.

Example

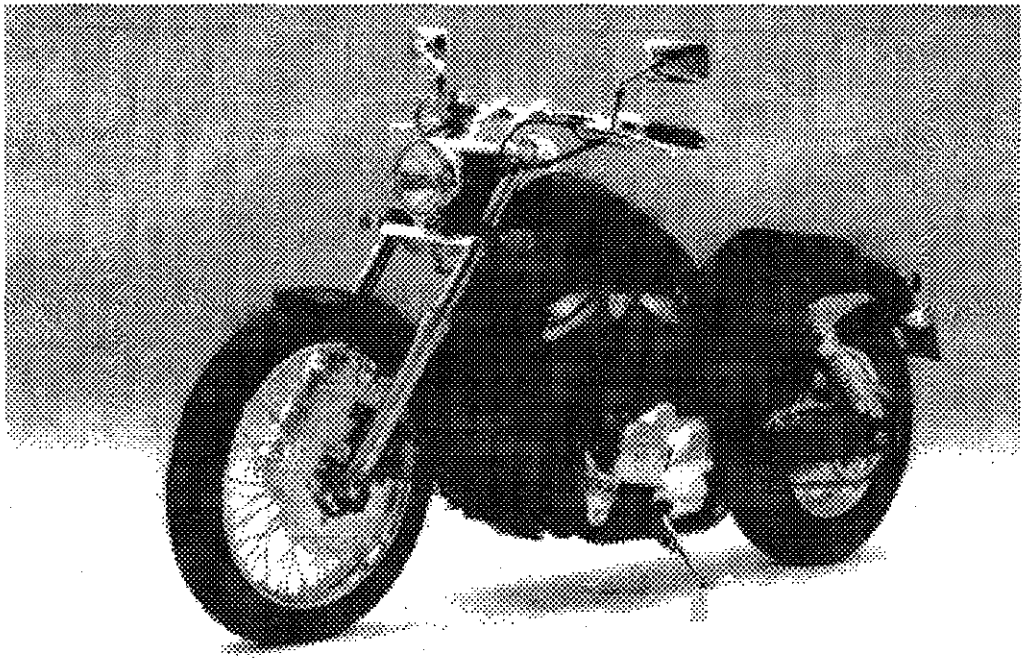

FIG. 1

Practice Tip

If possible, formal pen and ink drawings, clearly illustrating the exact shape and appearance of the design claimed, should be submitted with the application as filed.

If formal pen and ink drawings cannot be submitted with the application as filed, any informal drawings or photographs submitted should be reviewed to assure that the exact shape and appearance of all surfaces of the design claimed can be adequately understood.

Practice Tip - Shortening the Application

If a surface of an article is considered part of the claimed design but is not shown in the drawing since it is the same as or a mirror image of a another surface disclosed in the drawing, the specification as filed must clearly indicate such. Otherwise it will be understood that the claimed design is limited to the views shown in the drawing.

- An ornamental design may be embodied in less than a complete article. ***In re Zahn***, 617 F.2d 261, 204 USPQ 988 (CCPA 1980)

Any attempt to describe a surface not disclosed in the drawing or specification of an application as filed will be considered new matter.

Practice Tip – Use of Broken Lines

If broken lines are included in the drawing their use must be defined in the specification, i.e. environment, boundaries, stitching, fold lines, etc.

"Dotted and broken lines may mean different things in different circumstances and all we wish to say here is that in each case it must be made entirely clear what they do mean." *In re Blum*, 374 F.2d 904, 153 USPQ 177 (CCPA 1967).

Practice Tip – multiple embodiments in an application

If the disclosure of any embodiment relies on the disclosure of another embodiment for completeness to satisfy the requirements of 35 U.S.C. 112, first paragraph, the differences between the embodiments must be identified either in the figure descriptions or by way of a special description in the specification of the application as filed.

In the absence of a description of the differences between embodiments in the specification of an application as filed, the disclosure of one embodiment will normally not be permitted to provide antecedent basis for any written or visual amendment to the disclosure of other embodiments.

MPEP 1504.05 II. A.

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Review of Developments in Intellectual Property Law

October 2008 Volume 6, Issue 3

Inside this issue:

License Agreements in the Wake of *Quanta*: A Potential Need for Restructuring

On June 9, 2008, the Supreme Court decided *Quanta Computer, Inc. v. LG Electronics, Inc.*[1] At issue was whether the doctrine of patent exhaustion applied to the sale of components of a patented system, where such components must be combined with additional components in order to practice patented methods.[2] The Court held (1) that the patent exhaustion doctrine does indeed apply to method patents[3] and (2) that an authorized sale of an article that "substantially embodies" the patent exhausts a patent owner's rights under patent law.[4] The Court attempted to temper this holding by observing in a footnote that contract damages may be available to a patentee even where patent exhaustion operates to eliminate patent damages.[5] This concession comports with Federal Circuit law holding that "private parties retain the freedom to contract concerning conditions of sale," when that sale is conditioned upon a lawful restriction.[6]

In the wake of *Quanta*, patent holders should consider carefully constructing the conditions of sale so as to limit licensees' rights, as opposed to attempting to limit downstream third parties' rights that flow from the licensee. Likewise, licensees should negotiate royalty payments that account for the lower value of these restricted patent rights. In general, then, patent holders and licensees should consider reevaluating what is and is not "authorized" under their license agreement(s).

The *Quanta* Decision

Quanta settled a dispute between a group of

continued on p. 2

KSR – One Year Later

The Supreme Court decided *KSR International Co. v. Teleflex, Inc.*[1] a little more than a year ago. Since then, the patenting community has watched to see how the lower courts would interpret the decision. After all, *KSR* involved a relatively simple invention: electronic pedal sensors for computer-controlled throttles. What would *KSR* mean for the patentability of complex inventions in fields such as biotechnology, medicinal chemistry, digital communications, and nanotechnology?

KSR and the TSM Test

The Federal Circuit has long employed a teaching, suggestion, or motivation test (the so-called "TSM test"), under which a patent claim is only proved obvious if the prior art, the nature of the problem solved, or the knowledge of a person having ordinary skill in the art reveals some motivation or suggestion to combine the prior art teachings in a manner that renders the claim obvious. The TSM test played the central role in *KSR*'s legal drama.

Prior to reaching the Supreme Court, the Federal Circuit had reversed the district court's finding that the patented invention was invalid as obvious.[2] The defendant's obviousness argument had relied on combining the teachings of two separate references.[3] The district court found that the combination was proper because it was suggested by the nature of the problem to be solved.[4] Relying on the TSM test, the Federal Circuit ruled that the combination was improper because neither reference precisely addressed the problem that the invention allegedly solved.[5]

The Supreme Court reversed the Federal Circuit,

continued on p. 5

KSR – One Year Later

continued from p. 1

yet largely affirmed the utility of the TSM test; at the same time, the Court warned against application of the test in a manner that would result in "[r]igid preventative rules that deny recourse to common sense."[6] In reaching its conclusion, the Court provided several additional signposts that indicated its desire for a more flexible obviousness inquiry.

First, the combined references need not address the problem solved by the claimed invention.[7] Rather, any need or problem known in the field and addressed by the references can provide a reason to combine the teachings of the references.[8] These, however, are old maxims.

Second, the Court also considered the forces driving innovation as important in the obviousness analysis, stating, "[o]ften, it will be necessary for a court…to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.[9] And, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."[10] This sounds a lot like the suggestion or motivation to make a claimed invention under the TSM test.

Third, the predictability of a combination is more central to the obviousness inquiry than the source of the suggestion to make the combination. The Court noted: "[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, [the Patent Act] likely bars its patentability."[11] "A court must ask whether the improvement is more than the *predictable* use of prior art elements according to their established functions.[12] "Predictability" under *KSR* sounds a lot like reasonable expectation of success under the TSM test.

Fourth, if a combination is "obvious to try," then the claimed invention may indeed be obvious. The Court reasoned: "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense."[13] Similarly, the Court observed, "[i]n many fields it may be that there is little discussion of obvious techniques or combinations, and it may often be the case that market demand, rather than scientific literature, will drive design trends."[14] The Supreme Court showed that it is interested in preventing the awarding of patents for innovations that would occur in the ordinary course of events.

snippets.

It is unclear whether *KSR* has done much to change the law of obviousness.

KSR and the Federal Circuit

The Supreme Court granted *certiorari* in June 2006[15], and in the following months, the Federal Circuit began emphasizing a flexible nature of its TSM test. For example, in the 2006 case of *DyStar Textilfarben GmbH v. C.H. Patrick Co.*[16], the court emphasized that the TSM test "is actually quite flexible and not only permits, but requires, consideration of common knowledge and common sense."[17]

Furthermore, in *Pfizer, Inc. v. Apotex, Inc.*[18], the Federal Circuit abandoned its earlier requirement that the motivation to combine must be suggested by the combined references. In *Pfizer*, the Federal Circuit found the motivation to combine in a host of references that were themselves not part of the combination asserted against the patent.[19] Hence, in late 2006 and early 2007, the Federal Circuit appeared to preempt to some extent the Supreme Court's decision in *KSR* by anticipating many of the aspects of the Supreme Court's decision.

It is unclear, therefore, whether the Supreme Court's decision in *KSR* has done much to change the law of obviousness. Clearly, the Supreme Court has eliminated the TSM test as an absolute threshold for challenging a patent as obvious. This is especially true for rigid applications of the TSM test that required the combined references to suggest the desirability of their combination. The Supreme Court's decision in *KSR* has replaced such rigid applications of the TSM test with a perhaps softer focus on the reasons that may drive one of ordinary skill in the art to the claimed invention, as well as the predictability of successfully achieving it. But this is not substantially different from the TSM test.

In the following sections, we survey several cases in which the Federal Circuit has applied this new rubric, and discuss how the Supreme Court's decision in *KSR* may or may not have affected the result. We divide our discussion between chemistry/pharmaceutical cases and electrical/mechanical cases.

Chemistry/Pharmaceutical Cases

Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.[20], was one of the Federal Circuit's first post-*KSR* obviousness cases.

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KSR – One Year Later

continued from p. 5

The invention claimed by the asserted patent related to novel chemical compounds useful in the treatment of diabetes.[21] In *Takeda*, the claim at issue was directed to the compound pioglitazone, wherein an ethyl group is attached to the 5'-position of a pyridyl ring (see Figure 1). The alleged infringer argued that the claim at issue was obvious over the prior art compound b, which included a pyridyl ring with a methyl group attached at the 6'-position (see Figure 2).

Pointing to *KSR*, Alphapharm argued that it was "obvious to try" to modify the known compound to arrive at the claimed novel compound.[22]

The Federal Circuit rejected Alphapharm's argument, reasoning that *KSR*'s "obvious to try" language does not open the door to any speculative modification of a known compound.[23] Rather, modification of a known compound would be "obvious to try" if one of skill in the art could expect the modification to yield a predictable solution (*i.e.*, if there were a reason to expect the predicted result).[24] In this instance, there was nothing remarkable about compound b. In fact, it showed poor results as an antidiabetic agent and therefore taught away from its use as such a drug.[25] Thus, there would be no reason for a skilled artisan to modify compound b nor predictably expect that modifying it would lead to a compound having effectiveness as a diabetic therapy.[26] Thus, the Federal Circuit rejected a speculative "obvious to try" standard, and insisted on the central role of predictability. The Court agreed with the district court that Alphapharm had failed to establish a *prima facie* case of obviousness.

In *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*[27], the Federal Circuit applied a similar "predictability test" to declare a patented compound obvious. The patent's claims were directed to a purified stereoisomer of a particular compound useful as a treatment for hypertension.[28] It was already known that a mixture of the compound's various stereoisomers possessed efficacy for the same use.[29]

The Federal Circuit acknowledged that a purified compound is not always rendered obvious by a mixture containing the compound.[30] But the court noted that "if it is known that some desirable property of a mixture derives in whole or in part from a particular one of its components, or if the prior art would provide a person of ordinary skill in the art with reason to believe that this is so, the purified compound is prima facie obvious over the mixture even without an explicit teaching that the ingredient should be concentrated or purified."[31]

In *Aventis*, the court looked to an analogous series of stereoisomers that Merck had previously discovered.[32] In the Merck mixture, Merck scientists determined that a particular stereoisomer was the source of the mixture's therapeutic activity.[33] By using Merck's findings, the court held that one of skill in the art had reason to seek a stereoisomer primarily responsible for the activity, and could predictably determine which stereoisomer in the Aventis mixture would be responsible for the mixture's drug activity.[34] The court also noted that Aventis failed to show unexpected results sufficient to rebut the *prima facie* case of obviousness. Thus, the court emphasized predictability, but went outside of the immediate prior art to find the reason why the skilled artisan would select a particular stereoisomer from the mixture.

Finally, in *Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd.*[35], the court again considered

Figure 1

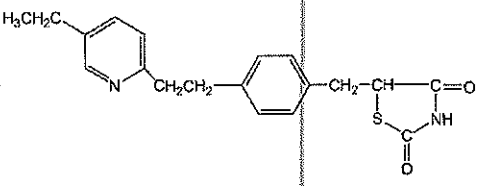
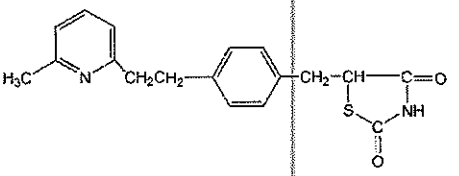


Figure 2



whether there was a reason to make the claimed compound at issue (rabeprazole) and predictability in achieving the observed results in view of a structurally similar prior art molecule (lansoprazole). Reddy's had argued that it would be obvious to modify lansoprazole to arrive at the structure for rabeprazole.[36] Reddy's, however, could point to no objective reason why such a modification would be desirable.[37] In responding to Reddy's speculative "obvious to try" argument, the Federal Circuit again emphasized that obviousness requires that any modifications of known compounds must achieve predictable results.[38] In fact, the Court suggested that this bar is relatively high for unpredictable chemical inventions: "[t]o the extent an art is unpredictable, as chemical arts often are, *KSR*'s focus on...'identified, predictable solutions' may present a difficult hurdle because potential solutions are less likely to be genuinely predictable."[39]

Electrical/Mechanical Cases

In recent cases involving consumer electronics, the Federal Circuit has embraced a post-*KSR* approach to obviousness that rejects rigid formulae in favor of more fact-oriented evaluations.[40] In *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*[41], the Federal Circuit noted that the goal of the asserted claim was to allow a child to press a switch associated with a single letter in a word and hear the sound of the letter as it is used in that word.[42] The Court reasoned that "[a]ccommodating a prior art mechanical device that accomplishes that goal to modern electronics would have been reasonably obvious to one of ordinary skill in designing children's learning devices."[43] Thus, when an invention involves no more than updating prior-art devices using modern electronic components, the invention will likely be found obvious in view of commonly available and understood art.[44]

In the absence of more rigid approaches, it may now be easier to challenge the nonobviousness of an invention by combining references to show that the particular invention is the predictable result of combining familiar elements in accordance with well-known methods.[45] In *Agrizap Inc. v. Woodstream Corp.*[46], the court noted that, as conceded by Agrizap, the only difference between a prior-art device and the asserted claims was a type of switch used to complete a circuit that triggers a function.[47] The asserted claims simply substituted a resistive electrical switch for the mechanical pressure switch employed by the prior-art device.[48] The court stated that objective evidence of nonobviousness in this case, including any substantial evidence of commercial success, praise, and long-felt need, was inadequate to overcome such a strong *prima facie* case of obviousness (*i.e.*, favoring resistive switches over mechanical switches is not a novel point).[49]

snippets.

Reasons to make an invention, as well as predictability in successfully doing so, have become important elements in the obviousness analysis.

Application of *KSR* to Prosecution of Patent Applications

With the new flexibility for applying the TSM test, and the acknowledgement of several new valid obviousness positions, patent examiners at the U.S. Patent and Trademark Office may begin applying 35 U.S.C. § 103 more broadly in the future. However, regardless of the permissible level of flexibility in an obviousness inquiry, the burden of establishing a *prima facie* case of obviousness during prosecution still remains squarely with the examiner. According to MPEP §§ 2142 and 2143, an examiner seeking to establish a *prima facie* case of obviousness must clearly articulate reasons with rational, factual underpinnings to support the conclusion of obviousness. Consequently, an obviousness rejection from an examiner is subject to attack on at least two bases.

First, an obviousness rejection may be overcome if the examiner did not clearly articulate reasons why the claimed invention logically follows from the teachings of the cited art. Under MPEP § 2142, conclusory or irrational statements are insufficient to establish a *prima facie* case of obviousness. It also appears that *prima facie* obviousness is not established when an examiner merely identifies claim elements scattered among several references. Rather, the examiner must logically establish at least one reason why a person of ordinary skill in the art would be lead to modify the cited art to achieve the claimed invention.[50]

Second, an obviousness rejection may be overcome by establishing that the factual underpinnings relied on by the examiner are flawed or insufficient. Clearly, an obviousness rejection cannot be supported by an examiner's erroneous interpretation of a reference. A case of *prima facie* obviousness is also not established by a summary of the teachings of a collection of references. Rather, the examiner must support a conclusion of obviousness by showing how the references teach or lead to the claim elements.[51]

Conclusion

In the year since the Supreme Court issued its decision in *KSR*, the lower courts have

continued on p. 8

KSR – One Year Later

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applied the opinion in several cases involving a range of technologies. Of course, the long-term legacy of *KSR* is still unknown, and the jurisprudence surrounding obviousness will continue to evolve as courts wrestle with *KSR* and its progeny. It seems clear, however, that reasons to make a claimed invention, as well as predictability in successfully doing so, have become important elements in the obviousness analysis. In that regard, *KSR* (and the manner in which the Federal Circuit applies it) may not have a significant impact on the obviousness analysis of complex technology.

Endnotes:

1. 550 U.S. ____, 127 S.Ct. 1727 (2007).
2. *Teleflex, Inc. v. KSR Int'l Co.*, 119 Fed.Appx. 282, 285 (Fed. Cir. 2005).
3. *Id.* at 286-287.
4. *Id.*
5. *Id.* at 288.
6. *KSR Int'l Co.*, 127 S. Ct. at 1732.
7. *Id.* at 1741.
8. *Id.*
9. *Id.* at 1740-41.
10. *Id.* at 1741.
11. *Id.* at 1740.
12. *Id.* (emphasis added).
13. *Id.* at 1742.
14. *Id.* at 1732.
15. *KSR Int'l Co. v. Teleflex, Inc.*, 548 U.S. 902 (U.S. 2006).
16. 464 F.3d 1356 (Fed. Cir. 2006).
17. *Id.* at 1367.
18. 480 F.3d 1348 (Fed. Cir. 2007).
19. *Id.* at 1362.
20. 492 F.3d 1350 (Fed. Cir. 2007).
21. *Id.* at 1353.
22. *Id.* at 1359.
23. *Id.*
24. *Id.*
25. *Id.*
26. *Id.*
27. 499 F.3d 1293 (Fed. Cir. 2007).
28. *Id.* at 1295.
29. *Id.* at 1301.
30. *Id.*
31. *Id.*
32. *Id.* at 1302.
33. *Id.*
34. *Id.* at 1302-03.
35. 533 F.3d 1353 (Fed. Cir. 2008).
36. *Id.* at 1357-58.
37. *Id.*
38. *Id.* at 1359.
39. *Id.*
40. *See Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007).
41. *Id.*
42. *Id.*
43. *Id.*
44. *Id.* at 1163.
45. *See Agrizap Inc. v. Woodstream Corp., 520 F.3d 1337* (Fed. Cir. 2008).
46. *Id.*
47. *Id.* at 1344.
48. *Id.*
49. *Id.*
50. *See* MPEP §§ 2142-2143.
51. *Id.*

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Benjamin R. Huber prepares and prosecutes patent applications, conducts legal research, and provides technological advice in support of validity, infringement and patentability analyses, patent application preparation and prosecution, and litigation matters in the electrical engineering field.

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713.05 Interviews Prohibited or Granted, Special Situations [R-5]

For Satu ... see MPEP § 713.01.

Except ... mitted aft ... applicatio ...

An inte ... first repl ... allowabl ... assist ap ... the pros ...

Offic ... or writt ... suspen ... applica ... agent i ...

Inte ... by persons ... character that there is serious question as to ... such persons are entitled to any information under the provisions of 37 CFR 1.14. In general, interviews are not granted to persons who lack proper authority from the applicant or attorney or agent of record in the form of a paper on file in the application. A MERE POWER TO INSPECT IS NOT SUFFICIENT AUTHORITY FOR GRANTING AN INTERVIEW INVOLVING THE MERITS OF THE APPLICATION.

Interviews are generally not granted to registered individuals who are known to be the local representatives of the attorney in the application unless a power of attorney >or Authorization to Act in a Representative Capacity (e.g., form PTO/SB/84)< to them is of record in the particular application. >See MPEP § 405.< Note that pursuant to 37 CFR 10.57(c), a practitioner cannot authorize other registered practitioners to conduct interviews without consent of the client after full disclosure. Furthermore, a practitioner can not authorize a nonpractitioner to conduct interviews since this would be contrary to 37 CFR 10.47.

While a registered practitioner not of record may request a telephone interview (if the practitioner is authorized to do so by the applicant or the attorney of record), it is recommended that a facsimile transmission of a power of attorney be filed prior to the interview. Otherwise, the examiner will conduct the telephone interview with the Office's file closed and work solely from the practitioner's file, which may be difficult to do over the phone.

Interviews normally should not be granted unless ... the requesting party has authority to bind the principal ...

... erviews in the "Con- ... ıe between the filing ...)ly and a concluding ... rneys resident or fre- ... area is obvious. For ... ɛ, electronic mail, or ... may prove valuable. ... places great emphasis ... ed by the examiner to ... See MPEP § 408.

... telephone call, may be ... bly quickly acceptable ... ı allowance. If there are ... ns, the call might state ... ı further telephone, electronic mail, or personal interview, at a prearranged later time, giving applicant more time for consideration before discussing the points raised.

For an interview with an examiner who does not have negotiation authority, arrangements should always include an examiner who does have such authority, and who is familiar with the application, so that authoritative agreement may be reached at the time of the interview.

GROUPED INTERVIEWS

For attorneys remote from the Washington, D.C. area who prefer personal or video conference interviews, the grouped interview practice is effective. If in any case there is a prearranged interview, *with agreement to file a prompt supplemental amendment putting the case as nearly as may be in condition for concluding action,* prompt filing of the supplemental amendment gives the application special status, and brings it up for immediate special action.

713.06 No *Inter Partes* Questions Discussed *Ex Parte*

The examiner may not discuss *inter partes* questions *ex parte* with any of the interested parties.

Norman Latker

From: Jay Finkelstein
Sent: Friday, April 04, 2008 10:12 AM
To: Sheridan Neimark; Patent Attorneys
Subject: RE: I need case law

The closest that I found is contained in the following excerpt from an amendment in Binder8Reex:

As stated in *In re Kotzab*, 55 U.S.P.Q.2D (BNA) 1313, 1316-17, (CAFC, 2000):

> Most if not all inventions arise from a combination of old elements. *See* *In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2D (BNA) 1453, 1457 (Fed. Cir. 1998). Thus, every element of a claimed invention may often be found in the prior art. *See id.* However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. *See id.* Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *See* *In re Dance*, 160 F.3d 1339, 1343, 48 U.S.P.Q.2D (BNA) 1635, 1637 (Fed. Cir. 1998); *In re Gordon*, 733 F.2d 900, 902, 221 U.S.P.Q. (BNA) 1125, 1127 (Fed. Cir. 1984). Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. *See* *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582, 37 U.S.P.Q.2D (BNA) 1314, 1318 (Fed. Cir. 1996).

It is noted that the rejection here under consideration is based on 35 USC §102. However, as should be self-evident, and as the CCPA noted in *In re Kalm*, 154 USPQ 10, 12 (1967):

> Necessarily, a description in a reference which is insufficient as a matter of law to render a composition of matter obvious to one of ordinary skill in the art would a fortiori be insufficient to "describe" the composition as that term is used

In re LUCK AND GAINER

U.S. Court of Customs and Patent Appeals
476 F2d 650
177 USPQ 523
No. 8842

Decided April 26, 1973

Headnotes

PATENTS

[1] Patentability -- Invention — In general (§ 51.501)

Under 35 U.S.C. 103 not only are teachings of prior art taken into consideration but also the level of ordinary skill in pertinent art.

[2] Claims — Article defined by process of manufacture (§ 20.15)

Product claims may include process steps to wholly or partially define claimed product; to extent these process limitations distinguish product over prior art, they must be given same consideration as traditional product characteristics.

Particular Patents

Particular patents—Lamp Coating

Luck and Gainer, Lamp Coating, claims 1 to 10 of application refused.

Case History and Disposition

Appeal from Board of Appeals of the Patent Office.

Application for patent of Russell M. Luck and Gordon C. Gainer, Serial No. 772,439, filed Oct. 25, 1968; Patent Office Group 160. From decision rejecting claims 1 to 10, applicants appeal. Affirmed.

Attorneys:

W. D. PALMER (BLAIRR. STUDEBAKER of counsel) both of Pittsburgh, Pa., for appellants.

S. WM. COCHRAN (FRED E. MCKELVEY of counsel) for Commissioner of Patents.

Judge:

Before MARKEY, Chief Judge, RICH, BALDWIN, and LANE, Associate Judges, and ALMOND, Senior Judge.

Opinion Text

Opinion By:

MARKEY, Chief Judge.

This appeal is from the decision of the Board of Appeals, adhered to *on reconsideration*, affirming the rejection of all the claims of appellants' application, serial No. 772,439, filed October 25, 1968, for "Lamp Coating," as unpatentable under 35 U.S.C. 103 over Pipkin [1] in view of Crissey et al. [2] and Boyd. [3] We affirm.

The Invention

The invention relates to an external coating for an incandescent lamp envelope (e.g. a Christmas tree lamp) which is adapted to both indoor and outdoor use and may be applied by a dip-coating process. The claims are drawn to the resultant coated glass envelope, claim 1 being representative:

> 1. A hollow light-transmitting lamp-bulb-shaped glass member adapted to surround a source of radiations, a coating carried on the external surface of said glass member, said coating comprising a mixture of:
>
> (a) a polymer consisting essentially of polymethylmethacrylate having a tack point temperature of at least 170°C. and an inherent viscosity of at least 0.44;
>
> (b) from 0.1% to 10% by weight of said polymethylmethacrylate of an organofunctional silane having organic functional groups and silicon functional groups, organic functional groups of said silane reacted with said polymethylmethacrylate and silicon functional groups of said silane reacted with the surface of said glass member to couple said polymethylmethacrylate to said glass member;
>
> (c) from 2% to 20% by weight of said polymethylmethacrylate of an additive

organic substance which is at least substantially transparent, has a boiling temperature at atmospheric pressure of at least 250°C., and is completely soluble in said polymethylmethacrylate polymer within the temperature range of from -40°C to 170°C.; and

(d) said coating having been affixed to said glass member by applying thereon a liquid organic solvent having dissolved therein said polymer, said organofunctional silane and said additive organic substance, and said coated glass member thereafter being baked.

Dependent claims 2-9 define limitations such as specific silanes in (b), organic substances in (c), or coloring substances. Independent claim 10 is drawn to the preferred embodiment, 0.3-3% of component (b) and 5-15% of component (c).

The Prior Art

The primary reference Pipkin discloses glass lamp bulbs externally coated with a lacquer composition which may be based on methacrylate esters. The coating is applied in a mixture of organic solvents, the solvents then being removed.

Crissey et al. disclose methylmethacrylate polymer coatings, pigmented or clear, for ceramic articles, wherein 10-50% by weight (based on the weight of the polymer) of a plasticizer is included. The correlation is set forth between plasticizer and physical properties of the coating, such as cracking, crazing, flexibility and durability. A solvent is employed in application and removed by air-drying or baking.

Boyd, though directed to size compositions for glass fibers rather than coatings for light bulbs, teaches the use of a coupling agent to promote adhesion to the glass fibers of the polymeric coating, which may consist primarily of polymethylmethacrylate. Organic silanes are described as suitable agents, with the nature of organic radical not being critical "except the greater the degree of compatibility with the resinous material, the greater the coupling power between the resinous material and the glass surface." In these particular compositions the silane coupler is present in amounts of 0.8-3.5% by weight, the polymer 1-7% and the aqueous carrier 75-98%.

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The Rejection

The examiner considered it obvious to modify the basic coating of Pipkin by including the silane coupler of Boyd to improve adhesion and the plasticizer of Crissey et al. to improve the physical characteristics of the coating. An affidavit submitted in an attempt to establish criticality for the upper limit of 10% for the silane in the present coating was found to be unpersuasive. Moreover, determination of optimum amounts of silane for a particular coating was considered within the realm of routine experimentation for one of ordinary skill in the art.

The process limitation set forth in part (d) of claims 1 and 10 was not regarded as

significant with respect to patentability of the claimed article for two reasons. First the organic solvent vehicle was no longer present in the product per se and second, an affidavit purporting to demonstrate the difference between the present coating and a coating using an aqueous vehicle provided no actual comparisons thereof.

In sustaining, the board agreed that appellants had failed to show that the use of a somewhat smaller ratio of silane to methacrylate (Boyd using a minimum of 11.4%) was significant. On *reconsideration*, the observation was added that "[i]t is a routine matter to determine optimum proportions for a given silane." The correspondence of appellants' ingredient (c) to conventional plasticizers was noted, a fact made evident by a review of the specification. On the matter of the process limitation, the board stated:

> * * * Insofar as the coated glass is concerned, it is immaterial whether the coupling agent was carried in water or in an organic solvent, since the carrier is no longer present in the finished article. In any event, we consider it obvious to use an organic solvent, because this is the vehicle in Pipkin and in Crissey et al.

Opinion

Appellants rest their case for unobviousness on the amount of silane coupler employed in the lamp coatings and the method of application, as set forth in the process limitation. It is urged that nowhere in the prior art is it suggested to use a silane coupler in the proportions employed by appellants or to apply a coating containing such coupler in an organic solvent. The disclosures of Boyd are said to lead only to the use of much greater amounts of the silane in an aqueous vehicle.

[1] We cannot accept appellants' contentions. The function of the silane in improving adhesion of polymeric material to a glass substrate was known, as was the effect of the plasticizer on the physical properties of the coating. Under § 103 not only are the teachings of the prior art taken into consideration but also the level of ordinary skill in the pertinent art. Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). In the present case, we must agree with the Patent Office that the determination of optimum amounts of the silane to achieve its recognized effect would lie within the ambit of ordinary skill in the art. The relevant affidavit of the coinventors evidences no more than routine testing to ascertain the most favorable proportions for this particular application. No critical upper limit is established. No unexpected result is demonstrated. Hence we find no basis for patentability in the amount of silane coupler.

[2] As for the method of application, it is well established that product claims may include process steps to wholly or partially define the claimed product. See In re Brown, 59 CCPA ____, 459 F.2d 531, 535, 173 USPQ 685, 688 (1972), and the cases cited therein. To the extent these process limitations distinguish the *product* over the prior art, they must be given the same consideration as traditional product characteristics. In the present case, we cannot agree with the Patent Office that the absence of the carrier in the final product renders the carrier immaterial. The method of application could well result in a difference in the coated article, regardless of the fate of the solvent.

But we do find that the Patent Office has established a prima facie case of obviousness for

the product even with full weight being given to the process limitation. The Pipkin and Crissey et al. references specifically teach the use of an organic solvent. Hence such a solvent is an obvious alternative to the aqueous carrier of Boyd, no criticality having been taught by Boyd for the combination of silane and water.

Appellants' affidavit alleging that the use of an aqueous vehicle would result in an "extremely poorly adherent and unsatisfactory" coating fails to provide the rebuttal evidence necessary to overcome this prima facie case. As pointed out by the examiner, no comparative tests are presented for evaluation. Accordingly, on the record before us, the process limitation adds no distinguishable characteristic to the claimed product.

The decision of the board is affirmed.

Footnotes

1 U. S. 2,781,654, issued February 19, 1957.

2 U. S. 2,934,509, issued April 26, 1960.

3 U. S. 3,082,183, issued March 19, 1963.

- End of Case -
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THE MEDICINE CHEST:
Non-Obviousness: Hope at the Board?

BY STEVEN R. LUDWIG, PH.D. OF VENABLE LLP

IP Today Columnist Steven Ludwig is a U.S. patent attorney with the law firm of Venable LLP in Washington, D.C. Dr. Ludwig's legal practice includes litigating and prosecuting pharmaceutical / biotech cases for his clients. He can be reached at 202-344-4690 or via email at sludwig@venable.com.

It is almost a year since *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) was decided and I have been wondering if the pendulum is continuing to swing in the direction toward rendering all biotech / pharmaceutical /chemical inventions obvious. After sifting through a few recent Board of Patent Appeals and Interferences decisions (December 2007 through January 18, 2008 (274 decisions — not a huge amount but enough to get a flavor of the opinions)), it appears that there may be a glimmer of hope - at least for now — that the pendulum is slowing or has stopped. Or maybe even reversing?

Following the U.S. Supreme Court's decision in *KSR*, Examiners had more arguments at their disposal to use when asserting an obviousness rejection against a claimed invention.

While there is no doubt that obviousness rejections continue to be frequently affirmed by the Board, I was pleased to find that a few Board decisions, some of which are discussed below, have reversed the Examiners' obviousness rejections and provided some guidance and a dose of optimism to patent practitioners and applicants.

For example, *Ex parte Wada and Murphy*, BPAI Appeal No. 2007-3733 (January 14, 2008) provides a nice description of what the Examiner is supposed to do when determining obviousness:

> As stated in *in re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):
>
> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability . . . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

When determining whether a claim is obvious, an Examiner must make a comparison of the claimed invention — including all its limitations — with the teaching of the prior art. *Ex parte Wada at 7*. The Board in *Ex parte Wada* cites *KSR at 1741* for requiring that "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

Thus, one theme found in Board decisions which reverse an Examiner's obviousness rejection is that "The Examiner has not articulated a sufficient reason why one skilled in the art would have modified [the art] and arrived at the presently claimed subject matter." *Ex parte Penhasi*, BPAI Appeal No. 2007-2534 (December 13, 2007). *See also, Ex parte Noelle et al.*, Appeal No. 2008-0011 (Jan. 15, 2008) and Appeal No. 2007-4358 (Jan. 3, 2008), The Examiner has the burden of articulating a *prima facie* case of obviousness and all too often ignores, or neglects, fulfilling this burden.

Another example of an Examiner not meeting his/her burden is found in *Ex parte Vatter*, BPAI 2008-0141 (December 12, 2007). Here, the Examiner assumed that the silicone elastomer of the reference had certain claimed properties. However, the Board found that the "Examiner assumes that the silicone elastomer of [the cited art] has the claimed properties . . . ." The Examiner "has not established with sufficient evidence" this belief.

Ex parte Fathman, BPAI Appeal No. 2007-4156 (December 11, 2007) dealt with the obviousness of claims directed to a method for treating autoimmune disease in a patient. Here, the Board harshly rejected the Examiner's arguments -"Contrary to the Examiner's intimation, the mere recognition that "[t]he genetic modification of cells has been routine in the art for some 20+ years" (Answer 5) does not mean that a person of ordinary skill in the art would willy-nilly modify any cell with any gene to treat a disease." The Board noted that "the inferences and creative steps derived from the prior art on this record fail to lead a person of ordinary skill in the art to Appellants' claimed invention. On this record, the Examiner has failed to identify a viable reason why a person of ordinary skill would have been led to combine the teachings of [the cited art] in the manner set forth in Appellant's claimed invention."

Another reason used by the Board to reverse an Examiner's rejection is "the unwitting application of hindsight" which is inappropriate. *Ex parte So and Thomas*, BPAI 2007-3967 (January 4, 2008). The Board in *Ex parte So* at 5 stated "there is nothing in the applied references which would have motivated an artisan to select this particular ingredient and then use the resulting composition . . . "

One case that I suspect might be cited frequently in the future is *Ex parte Atkinson and Benedict*, BPAI Appeal No. 2007-3900 (December 18, 2007). Here, the Examiner uses the common basis for rejection that it would have been obvious to one of ordinary skill in the art "to optimize . . . the workable ranges." The Board in reversing the Examiner states: "Optimization of a known result-effective variable in a given range is generally obvious, *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003); *In re Aller*, 220 F.2d 454, 456 (CCPA 1955), only when it is reasonably expected that an improvement will arise in that range."

As a final practice note, when preparing an appeal to the Board, it should be argued to the extent possible, that the claims do not stand or fall together. A good example of this strategy being used successfully is in *Ex parte Cohen*, BPAI Appeal 2007-4368 (December 31, 2007). This case had a number of claims which were argued separately and it was held that the Examiner simply did not meet his burden of establishing a prima facie case for each and every claim and thus, some of the Examiner's obviousness rejections were reversed.

In sum, it was nice to see after reviewing these cases, that the Board appears to be giving practitioners a road map for obtaining a favorable appeal. Bottom line — appeal! IPT

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United States: At The Razor's Edge: Prosecuting And Defending Against Patent Infringement Claims Post-KSR

22 January 2008

Article by Jeanne M. Gills

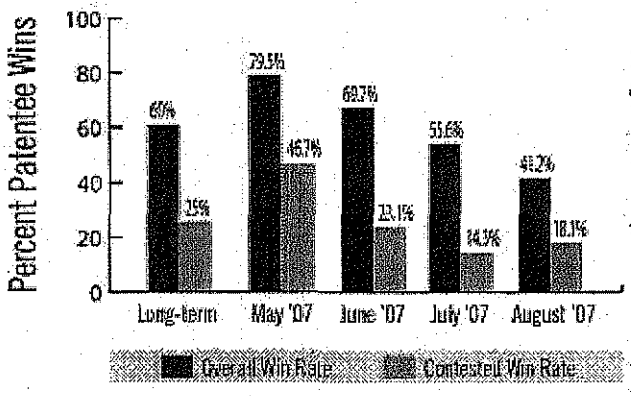
KSR Overview

While commentators might disagree over the magnitude of change, there is little dispute that the U.S. Supreme Court's *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (*KSR*) decision last year has impacted the manner in which plaintiffs and defendants have approached patent infringement claims. For years, practitioners largely relied on the case law driven "teaching-suggestion-motivation" (TSM) test in determining whether it was obvious to put together known elements in the art to meet the asserted claim. The Federal Circuit had likewise long-rejected any "obvious to try" standard. In *KSR*, the Supreme Court held that because the Federal Circuit applied its own TSM test too rigidly, the claim "must be found obvious." The Court further noted that TSM is a "helpful insight," but "when a court transforms the general principle into a ***rigid*** rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs."

This decision has and will continue to impact the ability to procure and defend patents on medical devices. The medical device arena necessarily involves the use of common elements and components — such as needles, pumps, and valves. Thus, *KSR*'s directive to exercise common sense and to afford the person of ordinary skill to art areas outside the medical field opens up potential new obviousness challenges that may not have existed before.

In particular, had the *KSR* court merely commented on the proper application of the TSM test, there may have been little fanfare. Instead, the Court expounded on several aspects of the obviousness inquiry: (i) ***Flexibility***: The obviousness inquiry is an "expansive and flexible approach"; (ii) ***Ordinary Creativity***: "A person of ordinary skill is also a person of ordinary creativity, not an automaton," who will not limit herself to art with the same problem, nor can she be confined to the problem patentee was trying to solve; (iii) ***Obvious to Try***: "[T]hat a combination was obvious to try might show that it was obvious under § 103"; (iv) ***Predictability***: The patent must be more than "the predictable use of prior art elements according to their established functions"; and (v) ***Design Need/Market Pressure***: Products driven by design needs or market pressures — when there are finite number of identified predictable solutions — are likely the result from ordinary skill, not innovation. In applying *KSR*, subsequent courts have quoted these tenets in their findings.

Post-*KSR* Patentee Win Rates



In the seven months since *KSR* was decided, its impact has been felt across many industries, with some industries facing tougher challenges than others. As the trend chart indicates, post-*KSR*, there was a decline in a patentee's overall win rate in the subsequent months following *KSR*, despite a brief upward trend that first month.

*** Data from LegalMetric, LLC**

Post-*KSR* Medical Industry Cases

Nonetheless, recent cases in the medical technology and medical devices arena show promise for patentees. In *Boston Scientific Corp. v. Johnson & Johnson*, No. 02-00790, 2007 WL 2408870 (N.D. Cal. 8/21/07), in denying summary judgment of obviousness on patents directed to catheters, the Court stressed the need to show that the prior art taught the claimed invention, and emphasized *KSR's* directive to look at the *Graham v. John Deere Co. of Kansas City*, 86 S.Ct. 684 (1966) (*Graham*) for secondary considerations of non-obviousness. In *Boston Scientific*, the first series of patents-at-issue were directed to a bilayered catheter tube design for balloon angioplasty catheters. The bilayered tube was made by co-extrusion of a nylon outer layer and a high-density polyethylene (HDPE) inner layer. Regarding these patents, the Court held that the patentee raised a triable issue as to whether the prior art taught the use of co-extrusion to create a bilayered catheter comprised of HDPE and nylon. Specifically, the patentee presented evidence that it was known that HDPE did not bond well with other materials, including nylon. *Id.* at *6.

The other patent-at-issue in *Boston Scientific* was directed to methods of forming a fusion bond between a catheter and a balloon with a laser, where the catheter and the balloon have high absorptivity. *Id.* Regarding this other patent, the Court found there was a triable issue whether catheter-balloon laser bonding was obvious. While the prior art disclosed a catheter made from bonding with PET balloons, the patentee proffered evidence that the prior art bonding was made using hot jaws and solvents. The prior art's passing reference to laser bonding — as one among eight possible techniques for attaching a catheter body to a balloon — thus failed to disclose a reason to try laser bonding, nor did it necessarily imply that laser bonding was a viable solution. Further, the technological state of laser bonding at the relevant time was unclear. Other prior art proffered by patentee indicated that one skilled in the art would not have considered lasers as a viable method of balloon-catheter bonding, and thus there was a triable issue of fact as to whether the relevant prior art taught away from the use of laser bonding. *Id.* at *7-8. Finally, the Court noted that *KSR*'s affirmance of *Graham* "mandated exploration of secondary considerations such as commercial success, long felt need but unresolved needs, and the failure of others to achieve the invention." *Id.* at *8. These secondary considerations also supported denial of summary judgment of obviousness.

In another recent case, *NMT Medical, Inc. v. Cardia, Inc.*, No. 04-4200, 2007 WL 3454403 (D. Minn. 11/8/07), the Court declined to accept defendant's supplemental expert report on obviousness where the defendant argued that the *KSR* decision came after its initial expert reports and summary judgment papers were due. The Court observed that authority had already existed (namely, *DyStar Textilfarben GmBH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006)) when defendant submitted its summary judgment papers and thus it could have preserved its obviousness argument for appeal. *Id.* at *2. *See also Cordis Corp. v. Medtronic Ave, Inc.*, No. 2006-1393 *et al.*, 2008 WL 60499 (Fed. Cir. 1/7/08) (declined new trial on obviousness based on pre-*KSR* jury instruction on application of TSM test that was not previously objected to).

The Federal Circuit also recently vacated a Board of Patent Appeals and Interferences (BPAI) obviousness decision in *In re Sullivan*, 2007 U.S. App. LEXIS 20600 (Fed. Cir. 8/29/07). That case involved a patent relating to antivenom composition used to treat venomous bites from a rattlesnake. The BPAI had affirmed the examiner's rejection of certain claims as obvious over two prior art references (that taught use of whole antibodies for use against rattlesnake venom and use of Fab fragments to detect venom of different snake). The Court of Appeals, however reversed the BPAI, finding that the BPAI had failed to give weight to the rebuttal evidence of record. That rebuttal evidence included expert and inventor declarations on why use of Fab fragments as antivenoms was expected to fail and how prior art taught away. *See also Ex Parte Noelle*, 2008 WL 55123 (the BPAI reversed the examiner's finding of obviousness on claims directed to a method for inducing antigen-specific T-cell tolerance where there was no evidence why a person of ordinary skill in the art would purify isolated CD4+ T-cells in view of the ex vivo example using bone marrow in Noelle's disclosure).

On the flip side, there have been several recent BPAI decisions (across many technologies) that have found the alleged inventions to be unpatentable as obvious, citing *KSR* favorably. *See, e.g., In re Translogic Technology, Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007) (aff'd BPAI decision of obviousness on claims directed to multiplexer circuits noting that "obvious variants of prior art references are themselves part of the public domain"); *Ex Parte Lewis*, 2007 WL 4591416 (BPAI 12/31/07) (aff'd examiner's obviousness rejection of certain claims involving wireless networks); *Ex Parte Loda*, 2008 WL 55121 (BPAI 1/3/08) (aff'd examiner's obviousness rejection of claims directed to monitoring a product and providing data to a user where the combination of references "would have resulted in a predictable solution that would have been within the technical grasp of one of ordinary skill in the art"); *Ex Parte Michaluk*, 2008 WL 55122 (BPAI 1/3/08) (aff'd examiner's obviousness rejection of claims directed to method of supplying metal material from a supplier or agent to a sputtering target manufacturer where the combined references fall "well within the boundaries of that which would have been within the grasp of one of ordinary skill in the art" given the "limited number of ways" to achieve the claimed result); *Ex Parte Yoakim*, 2008 WL 55124 (BPAI 1/3/08) (aff'd examiner's obviousness rejection of claims directed to a sealed beverage cartridge designed to be extracted under pressure).

Best Practices in View of *KSR*

Upon consideration of the recent cases, the following are best practice litigation pointers for plaintiffs and defendants in enforcing or defending patent infringement claims.

For Plaintiff/Patentee:	For Defendant/Alleged Infringer:
• Place more reliance on and substantiate secondary factors (e.g., commercial success, and so forth). Important to establish a nexus between commercial success and claimed invention. • Use experts to raise issues of fact (e.g., reason to combine, level of skill, and so forth) that require a jury to decide. Many cases post-*KSR* relied heavily on expert reports and testimony. • Establish that a combination of references yields unpredictable results. • Establish that the combination of prior art still does not demonstrate all claim limitations. • Focus on establishing a lower level of ordinary skill in the art, thereby creating a lower likelihood of a reason to combine elements. • Find instances where prior art teaches away from combining the elements. • Consider having the patent reexamined prior to litigation. If successful, it will be harder to invalidate in later litigation.	• Rely on experts to support theories! • Do not restrict the prior art search to references designed for solving the same problem as the patent allegedly solves. • Find a strong design or market demand in place that provided a reason to combine elements. • Check if there was a known problem in the field for which there was an obvious solution as encompassed by the claims look for predictable results. • See if the patent specification discloses a purpose that leads to a reason for the combination. • Focus on establishing a ***higher*** level of ordinary skill in the art, thereby creating a higher likelihood of a reason to combine elements. • Focus obviousness arguments in all three *Graham* factors. • Argue against presumption of patentability because patent prosecuted under rigid TSM test. • Determine whether a known and obvious technique was used to improve a device, resulting in a predictable use. • Consider summary judgment motions to decide obviousness issues. • Attack commercial success evidence.

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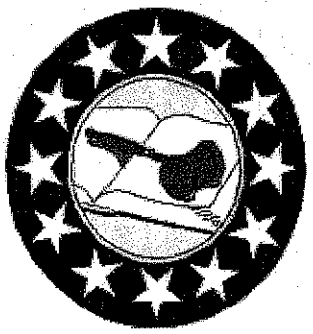

At The Razor's Edge

Jeanne M. Gills
date: Wednesday, January 23, 2008

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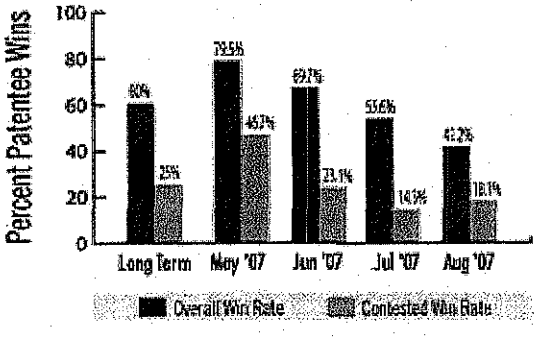

* Data from LegalMetric, LLC

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Nonetheless, recent cases in the medical technology and medical devices arena show promise for patentees. In *Boston Scientific Corp. v. Johnson & Johnson*, No. 02-00790, 2007 WL 2408870 (N.D. Cal. 8/21/07), in denying summary judgment of obviousness on patents directed to catheters, the Court stressed the need to show that the prior art taught the claimed invention, and emphasized *KSR*'s directive to look at the *Graham v. John Deere Co. of Kansas City*, 86 S.Ct. 684 (1966) (*Graham*) for secondary considerations of non-obviousness. In *Boston Scientific*, the first series of patents-at-issue were directed to a bilayered catheter tube design for balloon angioplasty catheters. The bilayered tube was made by co-extrusion of a nylon outer layer and a high-density polyethylene (HDPE) inner layer. Regarding these patents, the Court held that the patentee raised a triable issue as to whether the prior art taught the use of co-extrusion to create a bilayered catheter comprised of HDPE and nylon. Specifically, the patentee presented evidence that it was known that HDPE did not bond well with other materials, including nylon. *Id.* at *6.

The other patent-at-issue in *Boston Scientific* was directed to methods of forming a fusion bond between a catheter and a balloon with a laser, where the catheter and the balloon have high absorptivity. *Id.* Regarding this other

patent, the Court found there was a triable issue whether catheter-balloon laser bonding was obvious. While the prior art disclosed a catheter made from bonding with PET balloons, the patentee proffered evidence that the prior art bonding was made using hot jaws and solvents. The prior art's passing reference to laser bonding — as one among eight possible techniques for attaching a catheter body to a balloon — thus failed to disclose a reason to try laser bonding, nor did it necessarily imply that laser bonding was a viable solution. Further, the technological state of laser bonding at the relevant time was unclear. Other prior art proffered by patentee indicated that one skilled in the art would not have considered lasers as a viable method of balloon-catheter bonding, and thus there was a triable issue of fact as to whether the relevant prior art taught away from the use of laser bonding. *Id.* at *7-8. Finally, the Court noted that *KSR*'s affirmance of *Graham* "mandated exploration of secondary considerations such as commercial success, long felt need but unresolved needs, and the failure of others to achieve the invention." *Id.* at *8. These secondary considerations also supported denial of summary judgment of obviousness.

In another recent case, *NMT Medical, Inc. v. Cardia, Inc.*, No. 04-4200, 2007 WL 3454403 (D. Minn. 11/8/07), the Court declined to accept defendant's supplemental expert report on obviousness where the defendant argued that the *KSR* decision came after its initial expert reports and summary judgment papers were due. The Court observed that authority had already existed (namely, *DyStar Textilfarben GmBH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006)) when defendant submitted its summary judgment papers and thus it could have preserved its obviousness argument for appeal. *Id.* at *2. See also *Cordis Corp. v. Medtronic Ave, Inc.*, No. 2006-1393 *et al.*, 2008 WL 60499 (Fed. Cir. 1/7/08) (declined new trial on obviousness based on pre-*KSR* jury instruction on application of TSM test that was not previously objected to).

The Federal Circuit also recently vacated a Board of Patent Appeals and Interferences (BPAI) obviousness decision in *In re Sullivan*, 2007 U.S. App. LEXIS 20600 (Fed. Cir. 8/29/07). That case involved a patent relating to antivenom composition used to treat venomous bites from a rattlesnake. The BPAI had affirmed the examiner's rejection of certain claims as obvious over two prior art references (that taught use of whole antibodies for use against rattlesnake venom and use of Fab fragments to detect venom of different snake). The Court of Appeals, however reversed the BPAI, finding that the BPAI had failed to give weight to the rebuttal evidence of record. That rebuttal evidence included expert and inventor declarations on why use of Fab fragments as antivenoms was expected to fail and how prior art taught away. *See also Ex Parte Noelle*, 2008 WL 55123 (the BPAI reversed the examiner's finding of obviousness on claims directed to a method for inducing antigen-specific T-cell tolerance where there was no evidence why a person of ordinary skill in the art would purify isolated CD4+ T-cells in view of the ex vivo example using bone marrow in Noelle's disclosure).

On the flip side, there have been several recent BPAI decisions (across many technologies) that have found the alleged inventions to be unpatentable as obvious, citing *KSR* favorably. See, e.g., *In re Translogic Technology, Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007) (aff'd BPAI decision of obviousness on claims directed to multiplexer circuits noting that "obvious variants of prior art references are themselves part of the public domain"); *Ex Parte Lewis*, 2007 WL 4591416 (BPAI 12/31/07) (aff'd examiner's obviousness rejection of certain claims involving wireless networks); *Ex Parte Loda*, 2008 WL 55121 (BPAI 1/3/08) (aff'd examiner's obviousness rejection of claims directed to monitoring a product and providing data to a user where the combination of references "would have resulted in a predictable solution that would have been within the technical grasp of one of ordinary skill in the art"); *Ex Parte Michaluk*, 2008 WL 55122 (BPAI 1/3/08) (aff'd examiner's obviousness rejection of claims directed to method of supplying metal material from a supplier or agent to a sputtering target manufacturer where the combined references fall "well within the boundaries of that which would have been within the grasp of one of ordinary skill in the art" given the "limited number of ways" to achieve the claimed result); *Ex Parte Yoakim*, 2008 WL 55124 (BPAI 1/3/08) (aff'd examiner's obviousness rejection of claims directed to a sealed beverage cartridge designed to be extracted under pressure).

Best Practices in View of *KSR*

Upon consideration of the recent cases, the following are best practice litigation pointers for plaintiffs and defendants in enforcing or defending patent infringement claims.

For Plaintiff/Patentee:

- Place more reliance on and substantiate secondary factors (e.g., commercial success, and so forth). Important to establish a nexus between commercial success and claimed invention.
- Use experts to raise issues of fact (e.g., reason to combine, level of skill, and so forth) that require a jury to decide. Many cases post-*KSR* relied heavily on expert reports and testimony.
- Establish that a combination of references yields unpredictable results.
- Establish that the combination of prior art still does not demonstrate all claim limitations.
- Focus on establishing a lower level of ordinary skill in the art, thereby creating a lower likelihood of a reason to combine elements.
- Find instances where prior art teaches away from combining the elements.
- Consider having the patent reexamined prior to litigation. If successful, it will be harder to invalidate in later litigation.

For Defendant/Alleged Infringer:

- Rely on experts to support theories!
- Do not restrict the prior art search to references designed for solving the same problem as the patent allegedly solves.
- Find a strong design or market demand in place that provided a reason to combine elements.
- Check if there was a known problem in the field for which there was an obvious solution as encompassed by the claims look for predictable results.
- See if the patent specification discloses a purpose that leads to a reason for the combination.
- Focus on establishing a higher level of ordinary skill in the art, thereby creating a higher likelihood of a reason to combine elements.
- Focus obviousness arguments in all three Graham factors.
- Argue against presumption of patentability because patent prosecuted under rigid TSM test.
- Determine whether a known and obvious technique was used to improve a device, resulting in a predictable use.
- Consider summary judgment motions to decide obviousness issues. Attack commercial success evidence.

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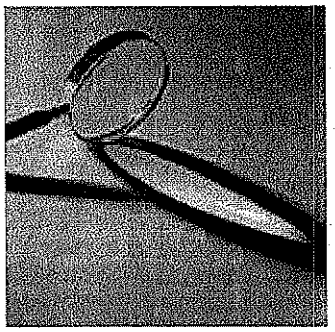

In re Lew "New Matter" and "Possession" Requirements

Harold Wegner
date: Friday, November 30, 2007

Today in *In re Lew*, __ Fed Appx. __ (Fed. Cir. 2007)(Gajarsa, J.), the court continued the misunderstanding of 35 USC § 132 "new matter" and its relationship to the 35 USC §112, ¶ 1, "written description" requirement.

The 1952 Patent Act as drafted – and today under 35 USC § 112, ¶ 1 – contains no "written description" requirement, *per se*. Rather, the "written description" language of the statute refers to the provision of an enabling disclosure – the sole objective disclosure requirement under that paragraph of the patent law.

Years after enactment in the 1960's, the "new matter" proscription of 35 USC § 132 was transformed into what was the "new matter" equivalent of 35 USC § 112, ¶ 1; eventually, with 35 USC § 132 being redundant, the predecessor court in 1981 in *Rasmussen* [cited in *Lew* as "1976"] threw out 35 USC § 132 as a basis for rejection: Examiners henceforth should rely upon 35 USC § 112, ¶ 1. The new matter proscription related only to new claim language as – obviously – an original claim is part of the application as filed and never could be subject to a new matter question.

In the 1990's, panels of the court judicially created a "possession" requirement even against original claims, as manifested in the cited *Noelle* case.

The *Lew* case is from one of the most experienced panels of the court involving three patent attorneys who have collectively been registered as patent attorneys and then served on the Federal Circuit for more than 100 years, all having been registered before the 1960's first modification of the practice. Yet, *Noelle* and the "possession" line of case law is blended together with a discussion of "new matter".

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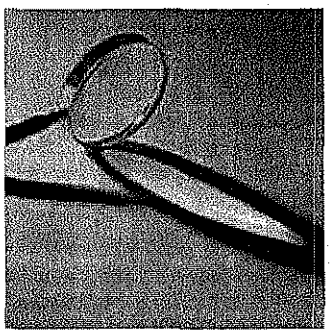

Is the Jaffe/Lerner Analysis of Patent Law Correct?

Lawrence B. Ebert
date: Monday, February 12, 2007

In response to my article concerning the book "Innovation and Its Discontents", one reader noted that I had not discussed the lengthy review of the Jaffe/Lerner book given by Professor Rochelle Dreyfuss in 104 Michigan Law Review 1559, which review comprised 20 pages and 92 footnotes.

In the context of my article, I was illustrating favorable reviews of the Jaffe/Lerner book which had appeared in the intellectual property literature. The Dreyfuss review is not wholly a favorable review. On the one hand, the Dreyfuss review states that "Adam Jaffe and Josh Lerner have given us a wonderfully timely book -- and also one that is beautifully executed," perhaps not the sort of thing Professor Field had in mind when he wrote in IPFrontline. The Dreyfuss review has some interesting lines (e.g., [The Jaffe/Lerner book] "uses as examples patents on inventions that are accessible to even the congenitally innumerate--the ubiquitous peanut butter and jelly sandwich..." On the other hand, the Dreyfuss review suggests that Jaffe/Lerner may have misunderstood the source of the problems, and Dreyfuss states there might be an institutional failure to keep patent law and policy abreast with developments at the technological frontier.

I have commented on the Dreyfuss review elsewhere "Rochelle Dreyfuss on Jaffe/Lerner Innovation and its Discontents" In the following, I will include some issues not raised by Professor Dreyfuss.

I. Why do we have a patent system?

If one can't agree on fundamental premises, later discussion about issues is difficult. Jaffe and Lerner lost me at "hello" when they stated: But at its heart, the patent system is about three things. It is about technology. It is about people. It is about how the rules and procedures established by Congress and the courts affect how the people interact with the underlying process of technological progress. [page 23] The patent system may involve technology, people, and laws and regulations, but the patent system is about DISCLOSURE OF INFORMATION. In return for disclosing information which meets the requirements of patent law, information disclosers (patentees) obtain certain rights. One notes that there has never been a requirement in patent law that a disclosure be of an invention that is commercially successful or changes the way we live (i.e., be an innovation). Scientific progress can be promoted by the disclosure of useful, novel, and nonobvious things which are not of commercial value. However, merely because an invention is not commercially successful does not mean one should build a repository of information of things which are not useful or not novel or are obvious. Thus, even when Jaffe and Lerner reject the "rational ignorance" approach of Lemley at pages 174-175, they do not place any value on having an accurate repository of information ["We agree with Lemley that it would be inefficient to provide thorough examination for all applications at the current rate of patent application. We disagree, however, that the current situation is acceptably efficient."] Jaffe and Lerner are more concerned with the economic disadvantage of bad patents then of the economic advantage of good patents. ["The intangible cost of a system with pervasive low-quality patents is much higher than just the cost of paying lawyers to file and defend patent cases."]

It is difficult to analyze the validity of a book which does not acknowledge the fundamental purpose of the patent system.

II. Did Jaffe and Lerner make their case about recent problems?

The thesis of Jaffe and Lerner is that two recent changes in the patent system have created current problems. At page 2, since 1982, the U.S. Congress made two adjustments in the way the patent system operates: creating the Court of Appeals for the Federal Circuit AND changing the financing of the PTO so that costs of operation are covered by fees paid by clients. Seemingly mundane procedural changes have produced the most profound changes in patent policy since 1836.

In a book trying to argue that two recent changes have created new problems, it is interesting to note the scarcity of information on "the way things used to be." One notes that Phyllis Shafly is mentioned 4 times (on pages 21, 158, 159, 162) as is G. Gordon Liddy (on pages 21, 151, 158, 159). The invention of the transistor (and the inventors Shockley, Bardeen, Brattain) and the invention of the integrated circuit (and the inventors Noyce and Kilby) are never mentioned. Charles Dickens and Robert Frost are mentioned, but Hugo Black, who might be deemed a philosophic godfather of the book, is never mentioned. Patent trolls are treated as a new development [A second worrisome development has been the emergence of individual inventors who seek to hold up established firms in their industries. In many cases, these individuals have received a patent of dubious validity, often with overly broad

claims. p. 15], but there is no mention of the Selden patent or the Ford litigation.

Even when some history is presented, the discussion is flawed. Jaffe and Lerner refer to Edison and the light bulb in the following way: Edison was granted the basic patent on incandescent lighting in 1880. Now, surely Edison's invention was about as novel as they get. [p. 49] The actual story of Edison and the light bulb shows that the invention was NOT as novel as they get, with an interference lost by Edison, deliberation at the Supreme Court (unmentioned by Jaffe and Lerner) and rights to earlier patents on light bulbs later bought by Edison. LOOK HERE for Edison as a Patent Troll, or Where is California Going in Stem Cell Research? Jaffe and Lerner get the story of the Wright Brothers wrong. They state: "After the Wright brothers patented their basic design (p. 50) for an aircraft stabilization and steering system, there were many others who wanted to work on a wide variety of different ideas for aircraft. But the Wright brothers refused to license anyone, and engaged in protracted litigation with a number of designers."

First, one notes that the Wrights did NOT refuse to license; they sought a royalty which many deemed too much. Second, at all times, the Wrights did NOT litigate against people who experimented with designs that might infringe their patent claims. They only went after people who sought to make money by infringing their patent claims. Jaffe and Lerner enter the land of make believe when discussing the later patent pool: "The rapid development of numerous different aircraft concepts in the years after the establishment of this 'patent pool' suggests that the unwillingness or inability of the inventors to cooperate with their technological followers temporarily retarded the development of technology." Because this fanciful view of history later infected intellectual property discussions on stem cells at CIRM, one should note a more accurate history. LOOK HERE for Patent thickets and the Wright Brothers

The "rapid development of aircraft concepts" in this time period happened in Europe because of World War I. By then, Wilbur Wright was dead and Orville Wright had sold his interests, so the "inventors" were out of the picture and disgusted with the patent system.

By ignoring and/or inaccurately depicting the past, Jaffe and Lerner did not make their case about present problems being of recent origin.

III. Bad patents

The theme of "bad patents" appears frequently in Innovation and Its Discontents.
For example, at page 20, The patent office has therefore found it difficult to attract and keep highly skilled individuals to do their important work. The result has been a torrent of poorly reviewed patents, pouring out onto a legal landscape in which even trivial patents can be wielded as potent litigation threats.

at page 22, The patent office has been granting patents on old ideas because it has inadequate examination resources and also because it is not very good at finding information about the relevant existing technologies, particularly in new, fast-moving technological fields.

Apart from anecdotal sound bytes, Jaffe and Lerner rely on some studies to support the idea of bad patents.

Beginning at page 142, Jaffe and Lerner write:

Cecil Quillen and his associates find evidence in support of this characterization of the situation in two recent studies. They point out that while the rejection rates for US patents appear impressive at first glance, these numbers are illusive. The false impression arises from the fact that when patent applications [sic] refile their proposals in response to an initial rejection by the PTO, in many cases this is counted as a fresh application. Fully one-quarter of the seemingly new applications are actually refilled rejected filings (more technically known as continuations), which means that the success rate is considerably higher. Because of ambiguities about the exact circumstances surrounding these additional filings, it is difficult to sort out exactly what is going on. (163). But putting aside the details behind the precise calculations, it seems clear that a very large fraction of applications are ultimately issuing.

Besides grant rates, there is another form of evidence for declining US patent quality that can be derived from international comparisons. Dominique Guellec and his colleagues at the Organisation for Economic Cooperation and Development (OECD) in Paris have been integrating data on patents granted by the U.S. PTO, the European Patent Office and the Japanese Patent Office.

And at page 143:

The OECD calculations indicate that the number of important inventions originating in the United States increased by 51% between 1987 and 1998. By comparison, the number of successful applications to the USPTO by US inventors increased 105% over the same period. If the examination standards in the United States were not changing, we might expect successful applications in the United States by US inventors to grow at about the same rate as our measure of internationally important inventions originating in the United States. The fact that the growth in successful PTO applications was, instead, twice as large as the growth of international families is hard to explain in any manner other than declining standards in the US PTO, producing an ever-growing proportion of US patents the patent holders themselves did not think merited patenting elsewhere.

Of the work by Quillen and Webster, there have been challenges to the methodology which produces grant rates in excess of 100%, first by Robert Clarke (not "George" Clarke as referenced by Jaffe and Lerner), and later by this

author, at 86 JPTOS 568, 88 JPTOS 239, and 88 JPTOS 726. Although Jaffe and Lerner were a bit vague about grant rate numbers in Innovation and Its Discontents, one notes a March 2006 editorial in the Wall Street Journal which was more specific: The editorial "Patently Absurd" (A14, March 1, 2006) depicts an out-of-control Patent Office approving almost 90% of submitted applications and a powerless court system constrained by a "clear and convincing evidence" standard. Of the OECD work, one notes that there can be many reasons, other than declining standards, to account for a change in a rate of growth.

In the end, the evidence for bad patents put forth by Jaffe and Lerner is less than convincing.

IV. Bad proofing

One wonders how carefully the book was proofed. For example:

The CAFC has interpreted patent law to make it easer [sic: easier] to get patents, easier to enforce patents against others, easier to get large financial awards from such enforcement, and harder for those accused of infringing patents to challenge the patents' validity. The new orientation of the patent office has combined with the court's legal interpretations to make it easier to get patents. [p. 2]

The false impression arises from the fact that when patent applications [sic] refile their proposals in response to an initial rejection by the PTO, in many cases this is counted as a fresh application. [p. 142]

true opportunity to prove invalidity before open-mined [sic] re-examiner. [p. 206]

In addition to citing to "George" Clarke, Jaffe and Lerner repeatedly misspelled the name of (later reviewer) Rochelle Dreyfuss. (for example, notes 33 and 67 refer to "Dreyfus".)

V. Good guys and bad guys

The intellectual property world of Jaffe and Lerner is populated by good guys and bad guys. At pages 35-37, Jaffe and Lerner identify both Qualcomm and Biogen as companies that use patents in appropriate manners. However, one notes that Qualcomm suffered a reverse in January 2007 in its attempt to use patents to control the H.264 standard.

Of Biogen, Jaffe and Lerner neglected to mention the case of NOELLE v. LEDERMAN, 355 F.3d 1343, 69 U.S.P.Q.2D 1508 (CAFC 2004), wherein Biogen and Idec were fighting over discoveries made with federal funding. SEE HERE and HERE

Rambus is targeted by Jaffe and Lerner as a company that engaged in an extended campaign to abuse the patent system, in large part because of its attempts to patent industry standards. [p. 69] Of Rambus v. Infineon, TechLawJournal gives a more accurate discussion of the Federal Circuit's decision than is found in Innovation and Its Discontents.
Rambus had sued Infineon asserting infringement claims of four of its patents, U.S. Patent Nos.

5,954,804 (based on a divisional of application Ser. No. 08/710,574, filed Sep. 19, 1996, now abandoned, which is a continuation of application Ser. No. 08/469,490 filed Jun. 6, 1995, now abandoned, which is a continuation of application Ser. No. 07/847,961 filed Mar. 5, 1992, now abandoned, which is a divisional of application Ser. No. 07/510,898 filed Apr. 18, 1990 now abandoned),

5,953,263 (based on a continuation of Ser. No. 08/798,520 filed Feb. 10, 1997, now U.S. Pat. No. 5,841,580, which is a division of application Ser. No. 08/448,657, filed May 24, 1995 (now U.S. Pat. No. 5,638,334); which is a division of application Ser. No. 08/222,646, filed on Mar. 31, 1994 (now U.S. Pat. No. 5,513,327); which is a continuation of application Ser. No. 07/954,945, filed on Sep. 30, 1992 (now U.S. Pat. No. 5,319,755); which is a continuation of application Ser. No. 07/510,898, filed on Apr. 18, 1990 now abandoned)),

6,034,918 (based on a continuation of application Ser. No. 09/196,199, filed on Nov. 20, 1998 (still pending), which is a continuation of application Ser. No. 08/798,520, filed on Feb. 10, 1997 (now U.S. Pat. No. 5,841,580); which is a division of application Ser. No. 08/448,657, filed May 24, 1995 (now U.S. Pat. No. 5,638,334); which is a division of application Ser. No. 08/222,646, filed on Mar. 31, 1994 (now U.S. Pat. No. 5,513,327); which is a continuation of application Ser. No. 07/954,945, filed on Sep. 30, 1992 (now U.S. Pat. No. 5,319,755); which is a continuation of application Ser. No. 07/510,898, filed on Apr. 18, 1990 now abandoned), and

6,032,214 (based on a continuation of application Ser. No. 08/979,127, filed Nov. 26, 1997, now U.S. Pat. No. 5,915,105, which is a continuation of application Ser. No. 08/762,139, filed Dec. 9, 1996, now U.S. Pat. No. 5,809,263, which is a continuation of application Ser. No. 08/607,780, filed Feb. 27, 1996, now abandoned, which is a continuation of application Ser. No. 08/222,646, filed Mar. 31, 1994, now U.S. Pat. No. 5,513,327, which is a continuation of application Ser. No. 07/954,945, filed Sep. 30, 1992, now U.S. Pat. No. 5,319,755, which is a continuation of application Ser. No. 07/510,898 filed Apr. 18, 1990, now abandoned.).

In turn Infineon counterclaimed for fraud under Virginia state law, based upon Rambus's non-disclosure to the JEDEC of its patents and patent applications related to the SDRAM and DDR-SDRAM standards. The reversal by the CAFC on the state law fraud claim, of great concern to Jaffe and Lerner, hinged on a finding: A party's silence or withholding of information does not constitute fraud in the absence of a duty to disclose that information. Although Jaffe and

Lerner wrote that the ruling on the fraud claim indicated that the judicial deck is stacked in favor of patentees (p. 74), it's difficult to see how interpretation of state law has anything to do with pro- or anti-patentee behavior by the CAFC.

To seek "anti-patentee" behavior by the CAFC, one need look no further than pre-Supreme Court decisions in the Festo saga, but, in this, one notes that assigning simplistic global labels based on particular cases can be tricky. Separately, the dissent in the CAFC was by Judge Sharon Prost, not Judge Payne, as incorrectly stated by Jaffe and Lerner on page 73.
A settlement between Rambus and Infineon was announced in March 2005.

At page 69 of Innovation and Its Discontents, in the context of a discussion of the Rambus case, Jaffe and Lerner presented a somewhat misleading discussion of divisional applications. The authors suggest that the filing of divisional applications allows the applicant to shape its patents according to evolving circumstances. In reality, divisional applications arise as a result of restriction requirements, issued by the Patent Office, forcing the applicant to break-up the initial claim set into separate claim sets, presented in different applications. Divisional applications can be filed only in response to an action by the Patent Office, so that they do not represent a strategic plan by the applicant to shape claims of patents in response to evolving circumstances. [See also 4 CHI.-KENT J. INTELL. PROP. 108 and 88 JPTOS 743.]

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Using KSR to Overcome an Obviousness Rejection

By Mark Nowotarski of Markets, Patents & Alliances LLC

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KSR vs Teleflex is turning out to be a surprisingly powerful tool for helping patent practitioners persuasively argue that their clients' inventions are not obvious. Recent decisions by the USPTO's Board of Patent Appeals and Interferences (BPAI or Board) can be used as templates for constructing these arguments. It turns out that the Board is citing KSR just as often when it reverses an examiner as when it affirms an examiner. Apparently, the more flexible approach of KSR cuts both ways.

There has been a tremendous concern among many in the patent bar over the implications of the recent US Supreme Court decision, KSR Int'l v. Teleflex Inc. With the Court using language like "expansive and flexible approach to the obviousness question", "Rigid preventative rules that deny recourse to common sense are neither necessary under, nor consistent with, this Court's case law", and "the results of ordinary innovation are not the subject of exclusive rights under the patent laws.", *KSR Int'l v. Teleflex Inc., 127 S. Ct. 1727, 1740-41, 82 USPQ2d 1385, 1396 (2007)* it seemed to many that the future of patents looked grim. These misgivings were only amplified when shortly after KSR, the CAFC rendered its Leapfrog decision stating, "Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not." *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 06-1402 (Fed. Cir. 2007)*

Fortunately, the recent decisions of the BPAI provide useful guidance on how effectively argue for the non-obviousness of a given invention in light of KSR. The decisions are available at www.uspto.gov/go/dcom/bpai. They can also be text searched through Google using the search string "site:www.uspto.gov/go/dcom/bpai" plus a key word or phrase, such as "common sense". With about 150 decisions per month being handed down by the BPAI directly related obviousness rejections, and with about 60% of these decisions citing KSR, there is ample material to see what sort of arguments are persuasive and what ones are not.

The Board has largely maintained its historical rate of reversals on obviousness rejections despite KSR. In the two months (March, April 07) immediately prior to KSR, for example, the Board found in favor of at least one claim of the applicant (i.e. examiner "reversed" or "affirmed in part") 34% of the time. In the two months (May, June 07) immediately after KSR, that number dropped somewhat to 28% of the time. The sky may have dropped down a notch or two, but it certainly hasn't fallen. Remember also, these post KSR decisions are being made on pre KSR arguments. There is about a one year backlog at the Board. These statistics could change, therefore, as both practitioners and examiners adapt their arguments to KSR requirements.

The Board seems to be using KSR citations in its reversals primarily to emphasize the necessity for an examiner to first make a proper prima facie case of obviousness before rejecting a claim. 75% of the reversals were based on either failure of the prior art to disclose an element of a claim or failure of the examiner to articulate an adequate rationale for combining the prior art to attain the claimed invention. Some representative language used by the Board is:

1. "There is no evidence or suggestion in _____ of such a configuration" *Ex Parte Katoh et al,* Appeal 20071460, Decided May 29, 2007

2. "Further, the Examiner has not provided any evidence that it was conventional in the art to_____" *Ex Parte Owlett,* Appeal 20070644, Decided June 20, 2007
3. "We determine that the Examiner has not provided a sufficient reason or explicit analysis of why the disclosures of the references should be combined." *Ex Parte Erkey et al,* Appeal 20071375, Decided May 11, 2007
4. "We find no suggestion to combine the teachings and suggestions of ___ and ___, as advanced by the Examiner, except from using Appellants' invention as a template through a hindsight reconstruction of Appellants' claims." *Ex Parte Crawford et al,* Appeal 20062429, Decided May 30, 2007

The Board is repeatedly citing KSR as it, in turn, cited In re Kahn.

> "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." (*In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) cited with approval in KSR)

This citation should be a powerful tool for practitioners and valuable guidance for examiners.

Effectively rebutting a prima facie case of obviousness, however, is still hard. The Board has used KSR in a few cases to point out that the common sense of one of ordinary skill in the art can be used to make an effective rebuttal. Two cases that have used KSR in this manner are *Ex Parte Rinkevich et al.* and *Ex Parte Green*. The representative language from these cases includes:

1. "In the instant case, we conclude that a person of ordinary skill in the art having common sense at the time of the invention would not have reasonably looked to _____ to solve a problem already solved by _____." *Ex Parte Rinkevich et al,* Appeal 20071317, decided May 29, 2007
2. "Therefore, we conclude that an artisan having common sense at the time of the invention would not have reasonably considered embedding a _____ within an existing _____ in the manner suggested by the Examiner." Ex Parte Green, Appeal 20071271, decided June 12, 2007

The Board cites KSR in these decisions as follows:

> "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of argument reliant upon ex post reasoning."

and

> "[r]igid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it." *KSR Int'l Co. v. Teleflex Inc.,* 127 S. Ct. 1727, 82 USPQ2d at 1397.

Despite these decisions, however, it still remains to be seen whether or not arguments related to the common sense of a person of ordinary skill in the art will become important tools for overcoming prima facie cases of obviousness.

The KSR versus Teleflex decision has been a wakeup call to many patent practitioners. The USPTO's Board of Patent Appeals and Interferences is citing KSR in close to 60% of its obviousness decisions. The overall reversal rate, however, has dropped only a little. The Board is citing KSR in its reversals to emphasize that a proper case for prima facie obviousness must include motivations to combine that are "articulated reasoning with some rational underpinning". Unsupported assertions are not adequate. The Board is also citing KSR to rebut prima facie cases of obviousness where "common sense" dictates that the claimed invention was not obvious. This is a new consideration that both examiners and practitioners will have to incorporate into their practices.

Sheridan Neimark

Monday, June 04, 2007

KSR and the BPAI: Analysis of Appeals for May, 2007

Over at the Fire of Genius blog, Joe Miller has been tabulating post-KSR decisions from the CAFC, the district courts and the BPAI (link) . Now that we have passed the one-month anniversary of *KSR*, how have Appellants fared at the USPTO?

Not so hot. For the month of May, Examiners have enjoyed a 64% affirmance rate on obviousness rejections.

The following list was made after reviewing 45 reported cases from the BPAI through May 29, 2007:

32 Appeals affirmed:

1. *Ex parte Teng*, 2007 WL 1378835 (BPAI May 10, 2007) (No. 2007-0954, Tech. Ctr. 2100)
2. *Ex parte Askeland*, 2007 WL 1418543 (BPAI May 14, 2007) (No. 2007-0960, Tech. Ctr. 2800)
3. *Ex parte Jha*, 2007 WL 1433429 (BPAI May 15, 2007) (No. 2007-0708, Tech. Ctr. 2100)
4. *Ex parte Toyoyama*, 2007 WL 1433430 (BPAI May 15, 2007) (No. 2007-0803, Tech. Ctr. 2800)
5. *Ex parte LeRose*, 2007 WL 1433432 (BPAI May 15, 2007) (No. 2007-1289, Tech. Ctr. 2100)
6. *Ex parte Almog*, 2007 WL 1451798 (BPAI May 15, 2007) (No. 2006-2968, Tech. Ctr. 1700)
7. *Ex parte Valiulis*, 2007 WL 1451799 (BPAI May 16, 2007) (No. 2006-3003, Tech. Ctr. 3600)
8. *Ex parte Amigh*, 2007 WL 1451803 (BPAI May 16, 2007) (No. 2007-0485, Tech. Ctr. 1700)
9. *Ex parte Mihalos*, 2007 WL 1451806 (BPAI May 16, 2007) (No. 2007-1390, Tech. Ctr. 1700)
10. *Ex parte Cohen*, 2007 WL 1460347 (BPAI May 17, 2007) (No. 2006-2886, Tech. Ctr. 2800)
11. *Ex parte Inala*, 2007 WL 1460346 (BPAI May 17, 2007) (No. 2007-0221, Tech. Ctr. 2100)
12. *Ex parte Elman*, 2007 WL 1460351 (BPAI May 18, 2007) (No. 2007-1204, Tech. Ctr. 3700)
13. *Ex parte Roseth*, 2007 WL 1460343 (BPAI May 18, 2007) (No. 2006-3311, Tech. Ctr. 3700)
14. *Ex parte Cheung*, 2007 WL 1460349 (BPAI May 18, 2007) (No. 2007-0717, Tech. Ctr. 2100)
15. *Ex parte Shin*, 2007 WL 146035 (BPAI May 18, 2007) (No. 2007-0002, Tech. Ctr. 1700)
16. *Ex parte Mangold*, 2007 WL 1511937 (BPAI May 21, 2007) (No. 2007-0088, Tech. Ctr. 1700)
17. *Ex parte Zimmerman*, 2007 WL 1494282 (BPAI May 22, 2007) (No. 2007-1308, Tech. Ctr. 3600)
18. *Ex parte Lacasse*, 2007 WL 1522947 (BPAI May 22, 2007) (No. 2006-2816, Tech. Ctr. 1700)
19. *Ex parte Atwood Mobile Prods.*, 2007 WL 1511938 (BPAI May 23, 2007) (No. 2007-0128, Reexamination No. 90/006, Pat. No. 5,573,648, Tech. Ctr. 1700)
20. *Ex parte Garelli*, 2007 WL 1511955 (BPAI May 23, 2007) (No. 2007-1922, Tech. Ctr. 1700)
21. *Ex parte Paulus*, 2007 WL 1511948 (BPAI May 23, 2007) (No. 2007-1104, Tech. Ctr. 2800)
22. *Ex parte Higashi*, 2007 WL 1511945 (BPAI May 23, 2007) (No. 2007-1004, Tech. Ctr. 1700)
23. *Ex parte Van Den Bergh*, 2007 WL 1511943 (BPAI May 23, 2007) (No. 2007-0835, Tech. Ctr. 2800)
24. *Ex parte Lee*, 2007 WL 1511941 (BPAI May 23, 2007) (No. 2007-0642, Tech. Ctr. 2600)
25. *Ex parte Goto*, 2007 WL 1522956 (BPAI May 24, 2007) (No. 2007-0693, Tech. Ctr. 1700)
26. *Ex parte Pisarsky*, 2007 WL 1522961 (BPAI May 24, 2007) (No. 2007-2005, Tech. Ctr. 3700)
27. *Ex parte Capoccia*, 2007 WL 1522959 (BPAI May 24, 2007) (No. 2007-1365, Reexamination No. 90/006, Pat. No. 6,289,548, Tech. Ctr. 1700)
28. *Ex parte Brookshire*, 2007 WL 1537599 (BPAI May 25, 2007) (No. 2006-2311, Tech. Ctr. 3600)
29. *Ex parte Rafal*, 2007 WL 1537602 (BPAI May 25, 2007) (No. 2006-3144, Tech. Ctr. 2100)
30. *Ex parte Clark*, 2007 WL 1537609 (BPAI May 25, 2007) (No. 2007-0561, Tech. Ctr. 2800)
31. *Ex parte Swanson*, 2007 WL 1537613 (BPAI May 25, 2007) (No. 2007-1765, Tech. Ctr. 1700)
32. *Ex parte Hubacek*, 2007 WL 1537606 (BPAI May 25, 2007) (No. 2007-0127, Tech. Ctr. 1700)

9 Appeals Reversed

1. *Ex parte Kalliokulju, 2007 WL 1378833 (BPAI May 10, 2007) (No. 2007-0834, Tech. Ctr. 2100)*
2. *Ex parte Erkey*, 2007 WL 1406641 (BPAI May 10, 2007) (No. 2007-1375, Tech. Ctr. 1700)
3. *Ex parte Umberger*, 2007 WL 1451804 (BPAI May 16, 2007) (No. 2007-0965, Tech. Ctr. 2100)
4. *Ex parte Mayer*, 2007 wl 1522953 (BPAI May 16, 2007) (No. 2007-0403, Tech. Ctr. 3700)
5. *Ex parte Napolez*, 2007 WL 1460353 (BPAI May 18, 2007) (No. 2007-1916, Tech. Ctr. 3600)
6. *Ex parte Bodin*, 2007 WL 1481832 (BPAI May 21, 2007) (No. 2007-0257, Tech. Ctr. 2100)
7. *Ex parte Diehl*, 2007 WL 1522949 (BPAI May 24, 2007) (No. 2007-0125, Tech. Ctr. 1700)
8. *Ex parte Katoh*, 2007 WL 1540192 (BPAI May 29, 2007) (No. 2007-1460, Tech. Ctr. 3600)
9. *Ex parte Rinkevich*, 2007 WL 1552288 (BPAI May 29, 2007) (No. 2007-1317, Tech. Ctr. 2100)

4 Appeals Reversed-in-Part, Affirmed-in-Part

1. *Ex parte Fokken*, 2007 WL 1540195 (BPAI May 16, 2007) (No. 2007-1565, Tech. Ctr. 1700)
2. *Ex parte Blanchard*, 2007 WL 1460352 (BPAI May 18, 2007) (No. 2007-1364, Tech. Ctr. 3700)
3. *Ex parte Ratcliff*, 2007 WL 1494281 (BPAI May 22, 2007) (No. 2007-1302, Tech. Ctr. 2100)
4. *Ex parte Nolte*, 2007 WL 1494275 (BPAI May 22, 2007) (No. 2007-0563, Tech. Ctr. 2100)

Thus, Appellants have managed to overturn obviousness rejections in only 36% of the Appeals decided in May. Notably, 2 of the affirmed 103 rejections were from reexamination requests (*Ex parte Atwood Mobile Prods.*, *Ex Parte Capoccia*) .

As Joe previously noted, the Board has overwhelmingly attached itself to the "precise teachings" and "inferences and creative steps" language used in the KSR decision:

> "[A]nalysis [of whether the subject matter of a claim is obvious] need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ."

In cases where the rejections were reversed, combinations were rejected by the Board when they were at odds with "common sense." For example,

> From these facts, there is no apparent reason to provide any phase change material (cooling medium), much less a phase change material having a different melting point, between two insulation layers. To do so would run counter to common sense of a person of ordinary skill in the art and the purpose of using the phase change material since the insulation layers would prevent the phase change material from performing its desired cooling function. Thus, contrary to the Examiner's contentions at page 4 of the Answer, we determine that a person having ordinary skill in the relevant art would not have been led to the claimed subject matter within the meaning of 35 U.S.C. § 103. (*Ex Parte Mayer*).

Ine one case, the Board found that the Examiner relied on improper hindisght reasoning in formulating the rejection:

> "In the instant case, we conclude that a person of ordinary skill in the art *having common sense* at the time of the invention would not have reasonably looked to Wu to solve a problem already solved by Savill. Therefore, we agree with Appellants that the Examiner has impermissibly used the instant claims as a guide or roadmap in formulating the rejection." *Ex parte Rinkevich* (emphasis in the original).

In a few cases (Ex Parte *Jha*, *Amigh*, *Mayer*), the Board relied on the CAFC *Dystar* and *Alza* decisions for the proposition that the obviousness test was "flexible" and "motivation need not be found in the references sought to be combined, but may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself."

In one interesting case, the Board affirmed the rejection despite a 1.132 declaration that argued unexpected results (*Ex Parte Hubacek*).

- To view individual decisions, see the USPTO e-FOIA page (link). Decisions may be searched by inventor

name, appeal no., application no., etc. Since the PTO severs these links after a short while, there was little reason to link each of the decisions in this post.

tions of U.S. chemical companies has magnified the changing pattern of capital spending within the U.S. At home, the parent chemical companies' spending still went up in 1976 from 1975 but only in line with inflation, according to Commerce and C&EN surveys. For 1977, capital spending surveys show a decline in planned increases in a level probably below inflation (C&EN, March 14, page 9).

Chemical capital spending outside the U.S. is running counter to the trend for U.S.-owned foreign affiliates in all industry. Spending for all industry is still expected to rise 12% in 1977 over 1976 to reach $28.9 billion, Commerce says. □

Francis Crick, others decide to leave U.K.

England is losing several distinguished chemists. Sir Francis Crick has decided to join the staff of Salk Institute in La Jolla, Calif., on a permanent basis. He has resigned from the U.K. Medical Research Council's Laboratory of Molecular Biology in Cambridge after 28 years there.

In June, fellow Nobelist Sir Derek Barton will quit London's Imperial College of Science & Technology. He will settle in Gif-sur-Yvette near Paris as director of Institut de Chimie de Substances Naturelles, part of the French government's Centre National de la Recherche Scientifique (CNRS). Following soon after will be Dr. Roger Parsons, a specialist in electrochemistry on the faculty of Bristol University. He will head CNRS's electrochemical laboratory at Bellevue, also a Paris suburb.

Considering the comings and goings of scientists of international renown, the move normally would pass all but unnoticed. But Crick's prominence—he shared the 1962 Nobel Prize in Medicine with Dr. James Watson and Dr. Maurice Wilkins for elucidating the structure of deoxyribonucleic acid—and the fact that he reputedly made his decision largely on financial considerations have magnified the event.

Friends of Crick say that a tightening of the U.K. tax laws in 1974 went far in prompting him to go. Until then, British residents weren't taxed on income earned outside the country so long as they didn't repatriate it. Now, such earnings are subject to taxation. The stricter ruling affects Crick and others like him who spend some of their time each year on the international lecture circuit or visiting research establishments in various countries.

Mandatory retirement at age 65, only four years off, was another factor in Crick's case. Because salaries of top academic people in the U.K. have been "frozen" for the next five years as part of the government's anti-inflation drive, he faced a pension that would have been unrealistically low taking into account yearly cost of living rises.

Dermot A. O'Sullivan, C&EN London

Government

New science adviser faces variety of problems

Calm, cautious, and judicious. That's how a Presidential science adviser should be, as the years have defined him, and that's just about how Dr. Frank Press was April 8 during his confirmation hearing as designated director of the Office of Science & Technology Policy. Press, appearing before the Senate Commerce, Science & Transportation Committee, gave a series of largely predictable answers to questions posed by committee chairman Adlai E. Stevenson Jr. (D.-Ill.) and Sen. Harrison Schmitt (R.-N.M.). Sen. Edward M. Kennedy (D.-Mass.) appeared briefly to introduce Press, a Massachusetts constituent, and ask him a few questions. Press is currently chairman of the department of earth and planetary sciences at Massachusetts Institute of Technology.

Press: impeccable credentials

Press' credentials as science adviser and OSTP director appear impeccable: member, National Academy of Sciences; past member, National Science Board; chairman, Committee for the Scholarly Communication with the People's Republic of China; adviser to the Arms Control & Disarmament Agency, Agency for International Development, Interior Department, National Aeronautics & Space Administration, and Defense Department. His expertise on the seismological aspects of nuclear testing don't hurt in an Administration bent on changing the rules of arms control.

As OSTP director, Press will be running a lean office, with at the most 20—possibly 15—professionals. President Carter will be organizing the White House staff and may merge OSTP with the Office of Telecommunications Policy, a prospect the current OSTP staffers believe would overbalance the office on the side of too much specialty in one field. OSTP has a host of formal duties that go well beyond the much looser function of the old Office of Science & Technology.

As science adviser and OSTP director, Press also will be chairman of three panels that come under OSTP: the Intergovernmental Science, Engineering & Technology Advisory Panel, the President's Committee on Science & Technology, and the Federal Coordinating Council for Science, Engineering & Technology. Press doesn't take over an organization begun de novo. Each of these groups was organized under Press' predecessor, Dr. H. Guyford Stever, whom President Ford named as full-time science adviser last summer. Press will be able to carry forth Stever's legacy and shape it to the Administration's own purposes.

The Intergovernmental Science, Engineering & Technology Advisory Panel, whose executive director is Louis Blair, was established under the OSTP Act to help improve the utilization of science and technology by state and local governments. It is composed largely of governors, mayors, and state legislators.

The President's Committee on Science & Technology, the outside advisory group similar to the old President's Science Advisory Committee, will be undergoing a sweeping membership overhaul, since its members were appointed during the previous Republican Administration. Its chairman, Simon Ramo, and vice-chairman, William O. Baker, have both left the committee, but Ramo has agreed to aid in the reconstitution of the group. He and Baker last fall put together a thick volume of issues developed by two panels assembled in 1975. Press will be using the tome's answers to such questions as OSTP's role in shaping patent policy as important homework in reviewing major issues in science and technology.

Finally, as chairman of the Federal Coordinating Council for Science, Engineering & Technology, Press will be responsible for developing policy positions for President Carter on issues that run across agency lines. The council currently is putting finishing touches on a report on climatic change and its consequences.

The work of an Office of Science & Technology Policy may appear to be general, since there are so many issues that must be dealt with. But each issue is obviously highly specific—such as the availability of uranium to meet light-water reactor needs now that Carter has decided to eliminate the breeder reactor program.

Thus, much will depend on Press' management style in running a small office with an enormously broad mandate. Says OSTP executive officer William Montgomery, "We'll have to be selective in what we tackle. We need a plan so objective that it can be laid out and the priorities set. And we must leave enough

resources available to deal with issues nobody can anticipate. If you don't have a plan you wind up reacting to external pressures all the time. We have to sit down and list the things we need to accomplish."

Press probably has all the lists he needs, especially with the issues book left him by the Baker-Ramo committee. At the moment, according to Montgomery, he is concentrating on establishing good working relations with the White House staff so that he has access to the President when he needs it. Very few Presidential advisers can reach the boss directly by dialing a telephone extension.

Press already has talked enough with the President to have reached a dialogue on top-priority issues. In statements prepared for the hearing, he said important steps had been made in reversing what he called the "downward trend" in the support of basic research. He said it was time to re-examine the industrial R&D effort to comprehend why that sector of R&D has not expanded. The entire subject of innovation will come into intense study during the Press regime, since the Administration is concerned about the eroding U.S. position in technological innovation.

Press says he intends to bring the scientific and engineering societies into the national science policy dialogue. He sees them as an "extended system of eyes and ears" monitoring emerging developments in science and engineering with their own professional concerns. He cites as a model of White House-society interaction the American Physical Society's study of nuclear reactor safety completed last year.

It is difficult to assess just what Press as a person, as science adviser, as scientist, can add to Presidential decision making. Problems have become more global, more intertwined, much more related to international economic policies than in the past, when international science policy in its mildest form related to scholarly exchanges and at its most intense to the arms race. Press, in other words, may indeed have to have a plan and a perspective to be more than just a yes man to the President.

It may well be that the test of his stewardship will be in advising on international relations and thus through his relationship with National Security Council head Zbigniew Brzerzinski. Brzerzinski has ideas of his own on the international ramifications of technology and its impact on the relations between nations. The challenge will be in the balance between economic and humanitarian motives in technology—or know-how—transfer. Know-how could well be used as a foreign policy tool—an item of trade or a lever to gain concessions. Press says he wouldn't favor holding back U.S. technology when meant for humanitarian ends.

It seems that it will be in the international economic area where his advice will most bear watching.

Wil Lepkowski, C&EN Washington

Climate study proposal gets mixed reviews

The freaky weather encountered across much of the country this winter, droughts in the West and record snow and cold in the East, has prompted efforts by the House Subcommittee on Environment & Atmosphere to shape a coordinated federal climate research program. The subcommittee's proposal got its first public airing earlier this month, but it did not draw rave reviews from Administration witnesses who appeared at the hearings, although all agreed climate research is a necessity.

The subcommittee's draft bill calls for spending an additional $50 million on climate research in fiscal 1976, including increased satellite monitoring of global climate conditions, basic research on ocean-atmosphere interactions, and the effect of human activities on climate. It also would set up a national climate program office, probably in the National Oceanic & Atmospheric Administration, to coordinate all federal climate research now scattered among a number of agencies. Within a year the office is to come up with a five-year plan detailing which federal agencies should be involved in climate research, how much funding and staffing is needed for the various programs, and specific milestones to be accomplished.

It sounds simple enough but the Administration isn't buying, at least for now. For example, Howard W. Hjort, director of agricultural economics for the Department of Agriculture, directly told the subcommittee that the legislation is not necessary. "In all good conscience," Hjort said, "I cannot support the provisions of the bill that assign the responsibilities for assessing the impact of climate on agriculture to another department, to a lead agency, or to a national climate program office." And NOAA administrator Robert White warned the subcommittee that a "crash program, no matter how lavishly funded, will not suffice." He also says t the "Administration is not prepared endorse all the specific provisions of t subcommittee bill."

Brown: ignorance about climate

Part of the problem between the A ministration and the subcommittee m be one of timing. An Interdepartmen Committee for Atmospheric Scienc (ICAS) consisting of representatives fr NOAA, USDA, the National Scien Foundation, the State Department, a the National Aeronautics & Space A ministration, among others, recent completed a draft proposal of its own o a national climate program. That propos has yet to be approved by the heads of th agencies involved or adopted by the Ad ministration.

As described by Dr. Edward P. Todd ICAS chairman, ICAS's draft recom mendations, although more detailed i content, sound much like those suggested by the subcommittee. They also show just how far is the U.S. from being able to predict or control the climate. ICAS identifies five categories in which priority research efforts are needed:

- Impact assessments of climatic variability on crop yields, energy demand, land and water resources, transportation, and other activities.
- Diagnosis and projection of observed climate variations, particularly seasonal and interannual anomalies and fluctuations.
- Research to gain better understanding of natural climate variability and of man's potential impact on climate.
- Observations by satellite and other means to help determine the earth's radiation budget, air composition, sea-air interactions, and other factors that induce climate variability.
- Management of the vast array of measurements needed for climate research and services—oceanic, atmospheric, hydrologic, solar, and other types of data.

Under the ICAS proposal, NOAA would be the lead agency for climate research but each of the other agencies involved would continue to set its own budget and obtain its own funding. Given the layers of clearance the ICAS proposals go through before they are adopted, it probably will be at least a year before the Administration can act on them.

However, despite lack of Administration support, subcommittee chairman George E. Brown Jr. (D.-Calif.) indicated at the hearings that the subcommittee probably will go ahead with its bill. He made the point that "a hesitancy to proceed with interdisciplinary and interagency efforts has prevailed for too long," adding that "the impact of climate variations is too great to allow another year to go by without taking some major steps toward reducing our ignorance about climate and climate change." Thus, the subcommittee hopes to have a final package ready by May 15, Congress' self-imposed deadline for reporting legislation containing new spending proposals for fiscal 1978. □

3515 Woodbine
Chevy Chase, Md. 20015

25.1
Free
Technology Transfer

Honorable Newton Steers
House of Representatives
510 Cannon House Office Building
Washington, D. C. 20515

Dear Mr. Steers:

It was a pleasure for me and my wife to meet you at the Autistic Society wine and cheese party. I very much hope your desire to serve on the Science and Technology Committee is fulfilled, since I believe that a number of interesting issues which involve the interface between Government funded research and industrial use of its end results will be emerging in the near future.

As I noted, Congressman Ray Thornton's proposed bill on Government patent policy is aimed at eliminating the over 22 patent policies now being administered by the Executive Branch and enhancing the possibility of commercialization of the results flowing from the 24 billion dollar Government research and development program. In addition, I understand that the full Committee intends to have hearings in late March on DNA research. It appears to me that the DNA issue will probably touch upon the ownership of end results from that portion of DNA research being supported by the Federal Government.

I am attaching, as you requested, a "Sampling of University Patent Licensing Programs". The innovations listed were initially generated with seed money from Department of Health, Education and Welfare's one and one-half billion dollar a year grant program to the non-profit sector. The sampling indicates that over 50 million dollars of private risk capital has been invested in developing or bringing these few innovations to the marketplace. The industrial involvement in each of these cases is based on the ability of the university to transfer a patent right to the licensee. Unfortunately, not all the agencies of the Executive Branch have patent policies which permit such university licensing, despite the fact that studies indicate that the university sector is licensing over 30 percent of the patent portfolio they hold, while the Government's performance indicates a licensing rate of its own portfolio of under 5 percent. The Government's poor performance in my mind is primarily due to the loss of the "advocate" of the innovation when the Government retains or destroys the intellectual property rights involved. As I noted to you orally, Congressman Thronton's proposed bill takes this problem into consideration.

This is a highly complex area that is difficult to explain in a short letter. If you should become a member of the Science and Technology

Committee, I would be happy to assist with additional information evidencing the need to enhance the transfer of technology resulting from Government sponsored research and development to the marketplace.

I would add that the enhancement of technology transfer could be important to the growth of development oriented industry serving public needs along Route 270 in Montgomery County, as opposed to what now appears to be primarily organizations which serve the needs of Government offices and laboratories in the vicinity. In other words, the satellite industrial concerns along Route 128 in Boston and around Stanford University are based on the development of proprietary ideas emerging from the non-profit sector in Boston and Stanford for use by the public, while the same type of product oriented organizations are not appearing along Route 270. This could be based on the fact that there appears to be little incentive to develop ideas emerging from the National Bureau of Standards, the National Institutes of Health, Energy Research and Development Administration, and the universities in the area because of the difficulty of establishing a proprietary position before committing private risk capital to further development.

I am also attaching for your review, time permitting, a copy of a presentation on "The Impact of Laws and Regulations on the Innovative Process," a subject which is emerging as a problem area in our society.

Sincerely,

Norman J. Latker

2 Enclosures

bss: Mr. David Eden

25.1

NJL

Dr. Mitchell
3/2/74

WASHINGTON UNIVERSITY

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TELEPHONE: AREA CODE 314
FO 1-7356

11 February 1974

PERSONAL CORRESPONDENCE

Mr. Norman J. Latker, Patent Counsel
Department of Health, Education & Welfare
Washington, D.C. 20201

Dear Mr. Latker:

The message re the cloud over exclusive licensing which you brought to the Dvorkovitz meeting was obviously a frustrating one for you personally and it will take time before the full importance of the Nader case and of opinions held by some legislators become clear to the academic community and to industry. In the meantime, I hope you realize that universities, industry and especially consumers are indebted to you for standing on principle rather than accepting the normal role of compliant civil servant with respect to the present and possibly future Nader obtained court decisions. Yours is the only audible, realistic and effective voice on the subject from the Executive Branch and should your support be lost we could only look forward to a return to the days when much less of the material benefits of Government research was reaching the public. A review of the GAO Report No. B-164031(2) and the Harbridge House Report under Department of Commerce Contract 7-35087 clearly shows how perishable are the lessons learned only six years ago.

We at Washington University became aware that we might be neglecting our responsibility to the public only two and one half years ago. Prior to that time the fine sounding but unproductive patent program was not encouraging creation, development or export of material benefits from research. Today we have successful arrangements with industry which are bringing new and improved pharmaceuticals and medical devices to the public. Of critical importance to the viability of most of these undertakings has been the mechanism of the short term exclusive license which is the key to attracting the risk capital available only from industry. In a minority of cases we find the unique nature of an invention allows and even demands non-exclusive licensing usually because a single firm cannot bring its full range of benefits to the public. In such cases we have not hesitated to pursue the non-exclusive approach. But the lesson is that without an ability to do exclusive licensing Washington University's outstanding biomedical research capability will in all probability return to conditions of a few years ago when it was not effectively delivering material advances to the public.

The Nader forces have announced an intent to extend their attack on exclusive licensing so as to strike at the heart of the licensing program of a university such as ours. Challenge in the courts will rest with you and others in the Executive Branch. Seeking of the Congressional authority to nulify Nader court victories will most certainly receive support from university officials and scientists through the channels available to them. However, I am concerned both with the problem of getting Congressional authorization sponsored and passed and especially with the time that this may take. What we face is more comparable to effecting a revision of the patent statutes than to influencing the outcome of an annual DHEW appropriation act.

In the meantime it would be most opportune and beneficial to all if your office would examine the capabilities you may already possess for partial relief. Those exclusive property rights acquired by the Government through operation of law (I understand the case law here is less than overwhelming) probably cannot be protected from Nader attacks. These rights, I understand, are limited (or could legally and properly be limited) to the very specific products and/or processes actually intended by the Government to be developed under a contractual agreement. These could be defined and specified in the award by the Government at the time of contracting. All inventions falling outside those specified would, by law, be the property of the contractor or inventor and their management could still be controlled by the agency through other provisions of the contractual arrangement. The problem of disposing of property acquired by the Government through contract provisions because of agency regulations (and not by action of the "hired to invent" case law) would be avoided without giving up control by the agency of the reasonable management of such property in the public interest.

It would appear that the possibilities here could be worthwhile in the area of research career development awards, training grants, fellowships, research grants and even in research contracts. Probably the greatest immediate value would be a further strengthening of the mutual confidence between your office and the universities.

You have our support and we shall try to make it as effective as possible.

Sincerely,

E. L. MacCordy
Patent Coordinator

ELM:dd

224-8946

DRAFT - July 17, 1978

Amended S-2466 does not correct objections to the creation of overlapping authorities in that portion of the bill that creates the National Center for the Evaluation of Medical Technology. The authorities of the Center appear to duplicate the funded authorities of the National Institutes of Health.

Review of the authorities of several Institutes of the NIH indicates an ability and appropriations in these Institutes to evaluate medical technology as envisioned by the new medical Center. For instance, the mandate for the NHLBI provides for:

> "Research into the development, trial and evaluation of techniques, drugs and devices used in . . . prevention of heart, lung and blood diseases."

Clearly, NHLBI could undertake and has undertaken with the consent of its Advisory Councils the review of the efficacy of coronary by-pass surgery which is repeatedly cited as an example for the need for the new Center. The study being conducted by the Cardiac Diseases Branch will run for four to five years and measure the difference in death rate between patients having the cardiac by-pass surgery and those who have been treated only medicinally. Other variables will also be measured. At the end of the test the safety and efficacy will be evident and whether its cost is justified.

The study has been in process since 1974 and involves an investment of $2 million annually to closely monitor 800-900 heart patients.

Proponents of the bill indicate that several HEW sub-units "conduct some research on medical services and procedures". In the Rogers hearing

on HR 12584, a bill similar to S-2466, it was determined that 120 million dollars annually were being utilized for clinical trials on such evaluations as:

The widely publicized diabetic retinopathy trial.

Studies on oral anti-diabetes agents.

Breast cancer screening.

Multiple risk factor intervention trial (hypertension, cigarettes and lipids).

Aspirin myocardial infarction study.

Beta-Blocker heart trial.

Coronary drug project (this project determined that clofibrate was not useful in the ~~proposed study~~ evaluate population)

Prenatal review of 50,000 children born between 1957 and 1965 to determine the ~~etiology~~ of cerebral palsy.

The last study has involved over 100 million dollars, which could ~~hardly~~ barely be covered by the proposed budget anticipated for the National Center. Evaluation of fetal electronic monitoring, an area which has come under criticism as increasing Cesarian deliveries of children although within the authority of the NICHD, it has not been undertaken. ~~Although~~ While admitting an increase in such Cesarians, there is no evidence that the children so delivered will not be healthier on a long term basis than those not so monitored. Theoretically, a small study involving five hospitals over a period of seven years to study such children is estimated to cost 20 million dollars.

If the Center is created, are the proponents of the bill ready to reduce the NIH budget by a corresponding amount and to alter the

authorities of the several institutes in order to assure against internal in-fighting over jurisdiction over an evaluation of a technology such as coronary by-pass.

If, as the proponents of this bill indicate, the Center "would have no regulatory authority and its findings would have no direct impact on any existing programs," why is the authority not provided to the Public Health Service presently not sufficient?

It appears clear that the steps necessary to coordinate NIH studies have already been taken and require no new legislative authority but creation of the new Center, as noted, will clash with many existing legislative authorities. The proposed bill has already created confusion amongst agencies such as HSA, HRA and NIH on what their responsibilities will be if the legislation is passed. Further, Dr. Richmond in testifying on HR 12584 expressed the view that it would be premature and disruptive for the Department of HEW to undergo ~~such~~ a major structural change without a more fundamental understanding of the complexities involved in technology assessment.

While the proponents of S-2466 de-emphasize that the National Center would have direct impact on existing Federal programs and costs, the House Committee noted that the Center for Health Care Technology "can have great influence in holding down health care costs, since a careful assessment of the health care technology by the Center will enable decision makers to make sophisticated and supportable determinations with respect to the rational distribution and utilization of new and existing health care technology." Since amended S-2466 and HR 12584 appear to be similar or identical in language, which philosophy will prevail? Most important - it appears that the evaluations now conducted by NIH would likely involve an ability to determine cost effectiveness.

...shes Mark ...OP Debate

...McCain illustrate sharp differences, ...n as race nears critical S. Carolina vote.

...NSTEIN
...BAK
...ES

...—In a debate ...deological and ...eorge W. Bush ...clashed here ...abortion, cam... taxes, the use ...the conduct of ...equently emo... downright an... ...ystallized the ...sified between ...their contest ...vo seemed like ...fight who had ...list of griev...ds—but were ...nching. ...abbed McCain ...ator ran this ...Texas gover...nton; McCain ...h crossed the ...earing with J. ...he leader of a veterans' group generally considered a fringe organization, who accused McCain of abandoning veterans.

"Now I don't know if you can understand this, George, but that really hurts, that really hurts. . . . You should be ashamed," said McCain, who spent five years as a prisoner of war in Vietnam.

Bush said that Burch had not been speaking for him, but he didn't disavow Burch's charges. And throughout the evening, Bush repeatedly argued that the senator from Arizona was guilty of the same sort of attacks he had condemned. "You're playing the victim here," Bush said pointedly toward the end of the debate. "Remember who called who untrustworthy." Bush even waved a flier he said McCain's staff had distributed that accused him of threatening Social Security.

The 90-minute session, sponsored by a local business group and moderated by CNN's Larry King, came four days before Saturday's

Please see DEBATE, A16

U.S. Officials Probe Cost of Genetic Decoder

By PETER G. GOSSELIN
and PAUL JACOBS
TIMES STAFF WRITERS

WASHINGTON—Federal officials are investigating whether the government was overcharged for gene-sequencing machines developed at Caltech and widely considered crucial to the coming genetic revolution.

Both the government and private companies are using the machines in a race to decipher the human genetic code. The outcome of the competition could determine whether the medical miracles that are expected to flow from the decoding will end up in public or private hands.

The genetic code determines human heredity, and newly emerging knowledge of it is expected to point to novel ways of diagnosing and treating such devastating disorders as cancer, heart disease and a host of hereditary conditions that have long defied treatment.

Central to the federal investigation is whether Caltech researchers used federal funds to develop the technology that makes the machines possible. If they did, Caltech may have violated a 1980 technology licensing law by charging more than allowed for the machines and could be forced to repay millions or perhaps tens of millions of dollars.

Officials have subpoenaed lab notebooks and other records of former Caltech researchers involved in the invention of the machine. They have also sought records from PE Corp., a Norwalk, Conn.-based company that has licensed the decoding technology from Caltech. The university holds several critical patents on the technology. The company effectively has an exclusive license for its use and has made about 80% of the automated machines sold to date.

The Department of Health and Human Services confirmed Tuesday that its inspector general's office has been conducting an investigation and that documents have been subpoenaed. A spokeswoman, Judy Holtz, refused to provide details of the probe.

Please see INVENTION, A12

...ing a stolen shopping cart.

One of the officers, Edward Larrigan, shot the 5-foot-1, 102-pound, mentally ill woman when she allegedly lunged at him with a 12-inch screwdriver, police have said.

Board President Gerald L. Chaleff, along with Commissioners T. Warren Jackson and Dean Hansell, said in a written statement that they recognized that Larrigan honestly believed that he was in imminent danger.

"However, the preponderance of evidence does not support that degree of threat based on the totality of the circumstances, including Ms. Mitchell's stature and age," the statement read. "We also believe that the officer had not exhausted all reasonable alternatives at the time he fired."

FOCUSING ON PHOTOGRAPHER
A judge will decide if a Times photographer must testify about North Hollywood shootout. B1

Commissioners Herbert F. Boeckmann and Raquelle De La Rocha, who found that Larrigan acted within policy, also issued a written statement supporting their view.

"In the final analysis, we find that the officers' perceptions of im-

Please see POLICE, A21

...Rampart ...

By JIM NEWTON
and TINA DAUNT
TIMES STAFF WRITERS

After months of confl... ...ralysis and mounting im... members of the Los Ang... Council on Tuesday fin... fronted the Los Angeles ... partment's Rampart scand... to write a blank check to ... Commission and its inspe... eral, who is charged with ... the LAPD's internal inve... and recommendations for ...

The inspector genera... Jeffrey C. Eglash, welc... council action, and said ... confer with commissio... their staff over the nex... days about the resources ... to do his work.

"We'll be coming up wi... of attack," Eglash said. "... complete, comprehensiv... ough review. . . . It's u... going to be the commissio... decide the scope of that."

Eglash received a hug... confidence from the co... Tuesday, when it voted t... fatal May 21 shooting of ... woman Margaret Mitchel...

Please see RAMPA...

...ominations Reflect ...w Schools Equally

...N

...1 (the unkind ... of the Roman ...given to sinfull... forward and ...emy of Motion ...iences divided ...s Tuesday be... material it has ... the more cut... at once would ...le as contend... ...en visible for ...s the academy ...d presumably ...o its roster. It ...wing patterns ...ces, who still ...aurs but have ... willingness to ...s out of films ...endent spirit.

Death Certificate Delay... Add to Grief in Air Cras...

■ Law: Relatives often wait months, unable to wra... important matters. 'You can't have any closure,' o...

By SORAYA SARHADDI NELSON
TIMES STAFF WRITER

The scenario is almost routine: A plane crashes and rescuers fan out in a frantic search for survivors. Soon, somber investigators confirm the obvious: No one is alive.

Yet, officially, no one is dead until a coroner issues a death certificate, or the courts a ruling.

For those left behind, the process often spells a long, torturous wait: More than three months for James Hurd, whose son, Jamie, died in the 1996 TWA crash off Long Island, N.Y. Close to six months for William Burke of Ponce Inlet, Fla., who lost his son, Sean, in the 1997 Korean Air crash in Guam.

"You can't have any... when it keeps going," ... Crow of Edmonds, Wash., ... her uncle and cousin in th... Air crash off Rhode Islan... tober. "When the world k... people are dead and that ... no survivors, why shou... families have to wait" for ... be pronounced?

In the case of Alaska ... that pronouncement could ... the next few weeks. The ... County Board of Supervis... Tuesday to petition Super... to issue a declaration tha... are dead.

The need for a death c... is more than an emotio... Without it, next of kin ar...

Please see FAMIL...

A Cyanide Spill Poisons More Than F...

 L.A. TIMES

INVENTION: Caltech Funding Comes Under Probe

Continued from A1

Both Caltech and PE adamantly denied that federal funds were used in the invention of the decoder, known as the four-color automated DNA sequencer.

Under the 1980 law, the government permitted universities and some businesses to win patents and take title to inventions made with federal funds, but with the proviso that Washington not be charged steep fees for their use. At least until recently, the government and government-funded scientists were far and away the biggest buyers of DNA sequencers.

Asked about the probe late Tuesday, both Caltech officials and PE executives predicted that it would bear no fruit.

In a written statement issued by its attorneys, the university acknowledged that it had received "a civil subpoena for documents pertaining to the invention of the DNA sequencer."

But the statement said: "Based on our evaluation of the historical record, which dates back some 25 years, we are confident that [Caltech] followed all proper procedures with respect to claiming the rights to the DNA sequencing chemistry and technology. There is no question that the invention that is the basis for the commercial DNA sequencer was funded by private grants. No federal funding was received or used to support this invention, and therefore the federal government has no rights to the invention."

Michael W. Hunkapiller, a former Caltech researcher who is now president of PE Biosystems, the PE subsidiary that makes the sequencers, took a similar position, asserting that development of the sequencer "had nothing to do with government funding."

"What's ironic is that we tried so hard to get government funding at the early stages of the project, and we were told consistently that they weren't interested," Hunkapiller said.

Behind the scenes, both the university and the company have mounted a fierce defense of their claims to the technology, providing researchers who have received subpoenas with lawyers and arguing in correspondence with federal officials that there is no basis for the probe.

But their efforts seem likely to

pribe.

But their efforts seem likely to be dogged by a trail of federal grant applications, scientific papers and other documents that specifically credit federal funds with helping to underwrite the invention of the four-color technology and embodying of it in a working machine.

For example, a 1985 application for $1.8 million in National Science Foundation money specifically said the money was being sought to develop a DNA decoder. A 1986 article in the scientific journal Nature that describes the new technology credited the foundation for supporting research that led to the invention. Caltech and the foundation both issued press releases and held a joint news conference in 1986 to unveil the machine.

The Caltech press release said, "Development of the DNA sequenator was sponsored by the National Science Foundation" as well as by grants from a group of private companies.

Caltech's and PE's efforts to deflect the government could also be complicated by the views of one of the sequencer's principal inventors, Lloyd M. Smith, a former Caltech researcher now at the University of Wisconsin.

Smith acknowledged in a telephone interview that he did not know exactly where the money to support his work was coming from when he was laboring over the decoding technology as a postdoctoral fellow in the Caltech labs of Leroy Hood during the mid-1980s. But Smith said the lab "was totally made of federal money."

Asked whether he and his colleagues could have invented the sequencer and made it work without federal funds, Smith said, "No, not in my opinion. The whole environment of the lab was permeated with federal funds."

The 1980 legislation, known as the Bayh-Dole Act, requires universities to report all inventions to the federal government if any taxpayers' dollars were used to develop the idea or reduce the invention to practice. In such cases, the government hands over title to the invention to the academic institution but retains a right to its use and is freed from paying royalties on it.

Over the years, federal auditors have complained that the require-

: Caltech Funding Comes Under Probe

ments were all too often ignored. That had little financial impact until the current age of biotechnology when a discovery could lead to a billion-dollar drug or the founding of a billion-dollar company.

Caltech's defense centers on the timing of a National Science Foundation grant to Hood's lab. Documents show that Caltech promised that, under the grant, new instruments "will be developed."

However, John Wooley, who managed the foundation's biological instrumentation program, said his agency approved the grant only after it was convinced it would work.

A team of experts, he said, looked at a prototype of the machine and "judged that it worked." But Wooley acknowledged that he could not assess whether, in the parlance of the Bayh-Dole Act, it had been "reduced to practice."

"I don't know what a lawyer would say," Wooley said. "I don't know what the nuances are about 'reduced to practice.'"

Beyond the details of the Caltech investigation loom a series of issues likely to crop up with growing frequency—and contentiousness—in the coming years.

After two decades of encouraging private-sector use of federally funded research findings, Washington is discovering that some of those findings are proving extremely valuable and increasingly costly for the government to make use of.

At $300,000 a machine, the DNA sequencer is a case in point and has been attracting the attention not only of investigators but also of politicians. "We have been looking into charges that the American taxpayers may have been overcharged for these sequencers," said Rep. Ralph M. Hall of Texas, the ranking Democrat on the House Science Committee.

Then there is the question of whether a new generation of discovery that is emerging out of a previous, federally funded generation of findings will end up in the public or private sector. Some believe that the most dramatic example is that of the soon-to-be-deciphered human genetic code.

The feat of deciphering the entire code is only now possible because of the development of the automated DNA sequencer. Before automated sequencing, cracking even a tiny portion of the code involved a tricky manual process that could take months to complete. Using the automated method, which depends on four fluorescent dyes that mark the chemical building blocks that make up DNA and can be read by machine, the same job can be done in a matter of hours.

Two groups are now using the automated sequencing methods developed at Caltech to decipher the entire code. The first is the federally funded Human Genome Project, which is making its findings immediately public by posting them on computer Web sites. The second is a PE subsidiary, Celera Genomics Group, which has said it will eventually release some of its findings to the public but seek patents on others and keep the rest as part of a proprietary database to which it will sell subscriptions.

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BROWDY AND NEIMARK, *Washington*—Continued

ber, Board of Governors, 1988-1990; ; American Bar Association; American Intellectual Property Law Association (Author: "PTO Affairs," column in AIPLA Bulletin, 1985-1987; Member, Ad Hoc Committee on PTO Automation, 1983—; Chair: Committee on Relations with Patent and Trademark Office, 1985-1987; Chair, Public Information Committee, 1994-1996). ***LANGUAGES:*** French. ***PRACTICE AREAS:*** Biotechnology Law; Pharmaceuticals; Chemistry Trademark Law. ***Email:*** BRWDYNMRK@DIGIZEN.NET

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OF COUNSEL

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DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
Office of the Director

OER

To: Larry Gilbert
From: Norm L.

Office of Extramural Research
Building 1 Room 144
Bethesda, Maryland 20892
(301)496-1096
(301)402-3469 - FAX
http://grants.nih.gov/grants/

February 22, 2000

TO: Extramural Staff

FROM: Deputy Director for Extramural Research

SUBJECT: Policy Announcement 2000-01: NIH Compliance Policy for Extramural Invention Reporting

Background: Extramural funding from NIH supports biomedical research in an effort to gain new knowledge that will lead to better health for everyone. This knowledge often manifests itself as intellectual property, i.e., unique findings that result in new products, materials and processes. In the past, ownership of these inventions vested with the Federal Government. As the government had no means to manufacture or commercialize these advances, Congress passed the Bayh-Dole Act in 1980 (P.L. 96-517). The Bayh-Dole Act allows grantee/contractor organizations to retain principal rights to inventions resulting from grants, cooperative agreements and contracts. The Act also contains a provision that the Government will receive a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced, the invention for or on behalf of the U.S. throughout the world. Consequently, NIH has a major responsibility in protecting, promoting, and monitoring inventions that result from the extramural research programs it funds.

It should be noted that fellowships and training grants, which are made by NIH primarily for educational purposes, do not contain provisions giving NIH rights to inventions, including any resulting income. However, trainees are often associated with a research project and when the project is a federally funded research grant, an invention stemming from this research is normally subject to invention reporting requirements.

To facilitate NIH and grantee/contractor compliance with these regulations and help ensure invention reporting compliance, NIH's Office of Policy for Extramural Research (OPERA), OER, developed Interagency Edison (IEdison) and Edison Report Lite (ERL). These two Internet-based systems allow, respectively, for grantee/contractor organizations to report and track inventions derived through NIH funding agreements, and for NIH IC staff to play a role in

monitoring grantee/contractor organization compliance, consistent with NIH grant and contract policy.

The purpose of this announcement is to broadly delineate the roles, responsibilities and involvement of extramural staff and provide general guidance for ensuring grantee/contractor compliance of the Bayh-Dole Act and related 37 CFR Section 401 regulations.

Policy Statement: NIH extramural staff must ensure that grantee/contractor organizations are in compliance with existing regulations regarding invention reporting and provide stewardship in protecting the government's rights to inventions funded through extramural research programs. Although the primary responsibility for oversight and monitoring extramural invention activities resides with the OPERA, OER, all extramural staff who administer grant and contract programs are responsible for understanding the laws and policies governing invention reporting and for ensuring that grantee/contractor organizations are in compliance with the Bayh-Dole Act.

Discussion: The Bayh-Dole Act is implemented through Department of Commerce regulations 37 CFR 401. These regulations define terms, parties, responsibilities, prescribe the order of disposition of rights, prescribe a chronology of reporting requirements, and delineate the basis for and extent of government actions to retain rights. The patent rights clauses are found at 37 CFR Part 401.14 and are accessible from the Interagency Edison web page, www.iedison.gov , and in the NIH Grants Policy Statement. In the case of contracts, Title 48, Chapter 1, Subchapter E, Part 27 of the Federal Acquisition Regulations (FAR), pertains to inventions and patents. The Standard Patent Rights Clause for use in contracts is contained in Subchapter H, Part 52 of the FAR. Terms and definitions relating to extramural inventions were published in the NIH Guide for Grants and Contracts, dated September 22, 1995, as a "20-20 View of Invention Reporting to the NIH" and are available at on the OER Extramural web site http://grants.nih.gov/grants/guide/index.html as a Guide Notice. This and other issues of the NIH Guide for Grants and Contracts referring to invention reporting and intellectual property are located centrally on the Grants Management Advisory Committee (GMAC) Infonet at http://odoerdb2.od.nih.gov/gmac/home.html under the Patents and Inventions link, as well as from the IEdison home page at http://www.iedison.gov/nihprocs.html . A timeline for invention reporting compliance is available at: www.iedison.gov on the NIH link under "FAQs and Information."

It is also important to consider how invention reporting will be conducted, the ethical issues involved in this process, as well as the need for confidentiality. Each of these topics will be discussed as follows.

Electronic Invention Reporting: The deployment of the extramural invention database system (originally known as Edison) in 1995, has improved invention reporting compliance processes at NIH. Beginning in 1998 Edison was renamed Interagency Edison (IEdison) as other Federal agencies adopted this electronic system for reporting, storing and monitoring their invention report documentation. This system meets all federally mandated invention reporting compliance requirements for both Federal agencies and their grant and contract recipients. A proactive messaging component of the system automatically alerts grantee/contractor organizations of compliance deadlines (i.e.,

election of title, patent deadlines, etc.) and other time sensitive reporting requirements (i.e., the automatic approval of time extensions, etc.). Edison Report-Lite (ERL) was developed as a companion system to accommodate the needs of NIH extramural managers and staff, the NIH Office of Technology Transfer, and IC public affair offices. The ERL interface includes the IEdison database invention report records submitted by grantee/contractor organizations with access provided for each specific I/C. Thus, ERL provides a mechanism for NIH staff to verify information.

Ethical Considerations: All NIH employees must avoid actual conflicts of interest and/or the appearance of such conflicts in so far as intellectual property rights are concerned. Extramural employees' impartiality may be questioned if they have funding or administrative responsibilities with respect to grantee/contractor inventorship. Employees are advised to consult their Deputy Ethics Counselor for guidance in this area. A list of these counselors can be found at **http://www3.od.nih.gov/ogcethics/findthe.htm** .

Confidentiality of Invention Reporting Documents: All information regarding inventions is very time-sensitive and proprietary in nature. Consequently, all documents relating to invention reporting must be considered highly confidential. Invention reporting information is normally exempt from disclosure, subject to the FOIA, and invention-related documents should not be routinely copied. Except as indicated below, documentation pertaining to inventions (i.e., "disclosures"), waivers, licenses, patent applications, etc., should **not** be filed in the IC grant or contract file. Rather, these documents should be forwarded to OPERA for inclusion in the IEdison system of records.

Roles and Responsibilities: Extramural invention reporting involves many organizational components and individuals at the NIH. The staff of grants and contracts management offices, extramural scientist administrators, IC technology transfer offices, OPERA staff, the NIH Office of Technology Transfer, and the NIH Office of General Counsel, HHS, all provide stewardship and oversight of the invention reporting enterprise. The following descriptions summarize the role of each of these components. Since responsibilities require concurrent or sequential interactions with other components, all parties should read this entire document.

Office of Extramural Research: OPERA serves as the primary point of contact for extramural invention reports, disclosures, confirmatory licenses, and other documentation required by the Bayh-Dole Act. To enhance compliance with Bayh-Dole requirements, OPERA develops policies and procedures; conducts training for extramural staff; and performs outreach to the extramural research community by conducting seminars and participating in regional and national meetings of professional societies related to research administration. These efforts also include preparing policy and informational announcements for the NIH Guide for Grants and Contracts and other NIH publications. OPERA also maintains and enhances the capabilities of IEdison and Edison Report-Lite

and provides user support for these compliance tools.

OPERA staff will monitor invention reporting by performing random compliance checks and conducting site visits with grantee/contractor organizations. Staff will work with representatives from the Council on Governmental Relations and the Association of University Technology Managers, Inc., as well as other national societies representing grantee/contractor organizations in an effort to improve understanding and compliance with the Bayh-Dole Act.

The address for the invention reporting function of OPERA is:

Chief, Extramural Inventions and Technology Resources Branch, OPERA, OER, NIH
6705 Rockledge Dr. Room 1136 MSC 7980
Bethesda, MD 20892-7980
(301) 435-1986
FAX (301) 480-0272; Email: edison@od.nih.gov ;
See also: www.iedison.gov for relevant information.

Grants Management Staff: Grants management staff play a vital role in protecting government rights to federally funded intellectual property. IC grants management staff should take every opportunity to remind grantees of their invention reporting obligations. Particular emphasis should be applied to recipients with limited grant funding experience (i.e., commercial organizations and small business entities). Toward this end, ICs are encouraged to include, at time of award, an informational letter that details invention reporting requirements. Such a letter is now routinely included with the Notice of Grant Award for SBIRs and STTRs. A copy of this letter is available internally from the Grants Management Infonet at: http://odoerdb2.od.nih.gov/gmac/topics/patents_main.html .

There are circumstances where special terms of award are warranted to ensure that any resulting invention will be made available for public use. Before implementing special terms and conditions of award, ICs should consult with OER.

If an invention report is included in a competing or non-competing grant application or on the Final Invention Statement and Certification (HHS 568), a search of the IEdison database should be conducted to verify whether or not any inventions have been reported under the specific grant number. Using the ERL interface (https://dali.cc.nih.gov/erl/), if the search shows *any* reported inventions, it will be assumed the grantee institution is reporting inventions and no further action will be required. If information regarding inventions as reported in the application is not consistent with IEdison records, OPERA must be notified via the ERL interface. OPERA will take any additional steps necessary to reconcile the discrepancy with the grantee organization. All actions taken by grants management must be documented and made part of the official file. A copy of an invention report from ERL or other information sent to OPERA is acceptable

documentation for the official grant file.

All invention related documentation (i.e., correspondence, disclosures, etc.) directed by the grantee to IC staff must be forwarded to OPERA for inclusion in the IEdison record system. The only exception is the HHS 568, which should be filed in the official grant file. However, if a copy of the HHS 568 reflects any inventions, a copy must be forwarded to OPERA for inclusion in the IEdison system of records.

Contract Management Staff: Contracts management staff must ensure that the solicitation and the contract document adequately describe the rights and responsibilities of the Government and the contractor with respect to inventions that may be made in the performance of work under the contract. This is accomplished by including the Patent Rights clause at FAR 52.227-11 and an Invention Reporting provision in the solicitation and the contract. If the work under the contract is to be performed outside of the United States, its possessions, and Puerto Rico, the contract and the solicitation will include the FAR clause at 52.227-13, in lieu of the clause at FAR 52.227-11.

Upon receipt of an annual invention report (only required if an invention has been developed during the reporting period), or a final invention statement reporting an invention, contract management is responsible for conducting a search of the IEdison database to verify whether or not any inventions are being reported under the specific contract number. Using the ERL interface (https://dali.cc.nih.gov/erl/), the contract manager will enter the contract number to query the IEdison database. If the search shows *any* reported inventions, it will be assumed the contractor is reporting inventions and no further action will be required. If an invention activity has been reported in either an annual or final report but has not been included in IEdison OPERA must be notified using the ERL interface. Beyond this notification, OPERA will take any additional steps necessary to reconcile the discrepancy with the contractor organization.

The annual and final reports are maintained in the IEdison record system, as well as in the official contract file. Any other invention related documentation (i.e., correspondence, disclosures, etc.) directed by the contractor to IC staff must be forwarded to OPERA for inclusion in the IEdison system.

Program Staff: Monitoring compliance for invention reporting is a responsibility that often requires scientific expertise. Review of a grant/contract application, including the scientific progress report, may reveal information that relates to the development of intellectual property (i.e., direct, indirect, or tangential references to the creation of an invention, a biological material, a unique research resource, etc.). An Extramural Scientist Administrator (ESA) possesses the scientific expertise to make a determination whether an invention is related to the research project and should be cognizant that references to commercialization, manufacturing, or marketing may be a result of NIH funding. In such cases the ESA must either inform grant/contract management staff of

this research outcome and grants management will take responsibility for seeing that the grantee/contractor fully complies with all reporting requirements, or the ESA will fulfill this function by conducting a search of the ERL system to establish whether or not this research outcome has been reported to NIH. If necessary, the ESA will obtain additional information from the grantee/contractor and see that an invention report is filed, if appropriate, and properly document the official file. If necessary, grant/contract management staff may assist in these efforts, as may OPERA staff.

Program staff must avoid any actual, apparent, or perceived conflict of interest with regard to their role as scientific advisor to grantees and contractors. ESAs who provide expert advice to grantees/contractors, or become co-inventors, must be aware of ethical issues and avoid impropriety. Recusal of any funding decision or program responsibility would normally be appropriate.

NIH Office of Technology Transfer: The Office of Technology Transfer (OTT) has the predominant responsibility for policy development and interpretation and administration of NIH intramural intellectual property. The office also has responsibility for providing guidance and consultation on interpretation and application of extramural technology transfer policy and procedures.

OTT provides assistance to NIH extramural awarding units to resolve technology transfer problems, including Declarations of Exceptional Circumstances (DEC), contents of Requests for Applications (RFA), Requests for Proposals (RFP), and application requirements. In coordination with other offices in the Office of the Director, NIH, OTT also prepares documents requesting assistance from HHS, PHS and provides assistance to grantee institution officials and others on extramural technology transfer policy matters.

Additionally, OTT has been delegated authority for extramural inventions in four areas: (1) election of title or assignment of title to an extramural invention on behalf of the government; (2) waiver of the preference for domestic manufacture (i.e., no contractor or grantee or their assignee shall grant to any person the exclusive right to use or sell a subject invention in the United States unless that person agrees that any products embodying the invention or produced trough its use will be manufactured substantially in the United States; (3) retention of title by the inventor; and (4) initiation and pursuit of government *march in* rights.

OTT's expertise is necessary in these areas due to the technical, legal and scientific ramifications associated with rights to intellectual property and the need to promote commercialization opportunities.

Technology Development Coordinators (TDC): The role of an IC TDC is to review extramural inventions where rights have been waived by the grantee/contractor organization and where the IC has an express interest in the invention. Inventions that are abandoned or waived by the grantee/contractor organization are reviewed by the TDC for

any possible IC interest. Results of these reviews are forwarded to OPERA, and the IEdison database is updated to reflect a change in status.

Special Programs Office, OER: The Special Programs Office provides the administrative oversight for the annual Omnibus Solicitation for SBIRs and STTRs. This office provides basic information for this community needed to comply with the requirements of the Bayh-Dole Act. This office also provides information through a Web site for small business organizations at http://www.nih.gov/grants/funding/sbir.htm.

Office of General Counsel: This office acts as the legal advisor to NIH on any issue where NIH's position or rights to inventions are involved.

This policy announcement is effective upon signature.

/s/
Wendy Baldwin, Ph.D.

Issuing Office: OER/OPERA (5-0949)

cc:
IC Directors
EPMC
POPOF
RPC
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OTT
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