Center for the Protection of Intellectual Property
&
Wisconsin Alumni Research Foundation

From Lab to Market: *How Intellectual Property Secures the Benefits of R&D*

March 21, 2014

#LabtoMarketIP

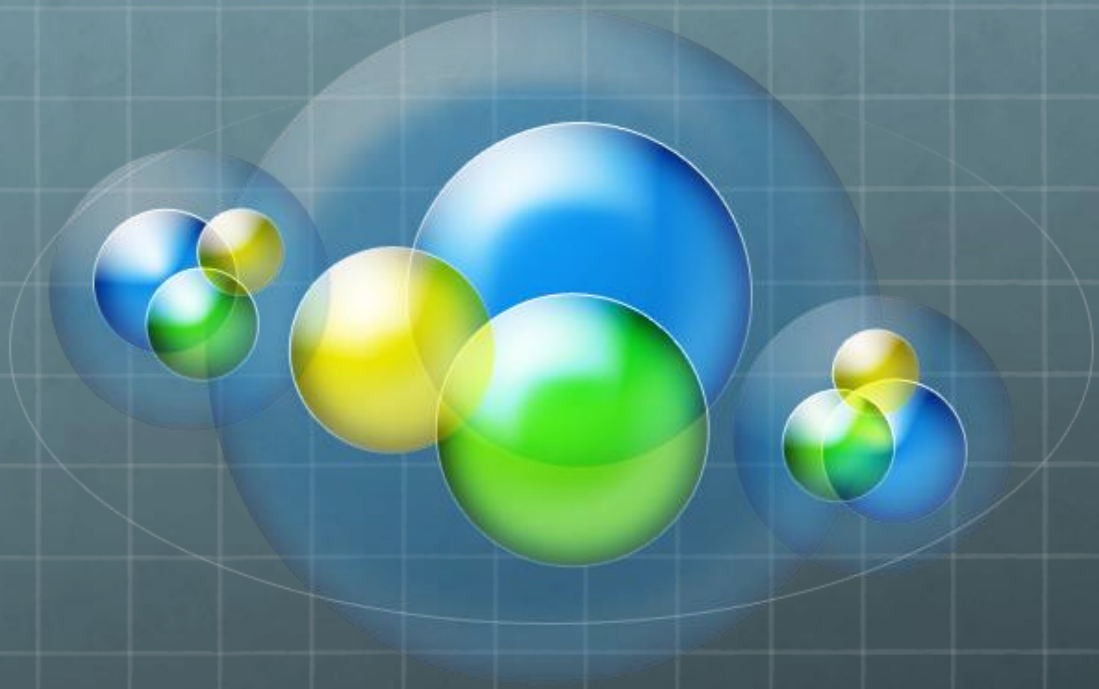
GEORGE MASON UNIVERSITY

Where Innovation Is Tradition

Panel 1 *University IP as a Driver of Economic Development*

- Prof. Stuart Graham, Georgia Tech University
- Prof. Sean O'Connor, University of Washington School of Law
- Dr. Laura Strong, *President and COO*, Quintessence Biosciences
- Michael Waring, *Executive Director of Federal Relations*, University of Michigan
- *Moderator*: Dr. Winslow Sargeant, *Chief Counsel for Advocacy*, Small Business Administration

#LabtoMarketIP



Tech Transfer and IP

How University Research Impacts Regions and the Importance of Patents to our Future

Three Issues to Cover

1. REGIONAL IMPACT OF TECH TRANSFER AND ITS VALUE
2. THE GROWING NEED TO TELL OUR STORY TO POLICYMAKERS AND THE PUBLIC
3. CURRENT CHALLENGES TO THIS PROCESS FROM CONGRESS AND THE ADMINISTRATION

Regional Impact

- Hugely important factor
- AUTM data shows that of initial phase of product development, over 70% of it occurs right around the university where the discovery was made
- One of the biggest selling points we have
- The ability to turn federal research funding into jobs and job creation helps focus members of Congress on why they should support these agencies
- Universities still major places for BASIC research

University of Michigan

- A research "powerhouse"
  - $1.3 billion in research expenditures
- In 2013, U-M research led to:
  - 421 new inventions
  - 108 licensing agreements with existing and new businesses
  - 9 new startups
  - 128 patents issued
  - $14.4 million in licensing revenue

Last Ten Years

- 3,246 inventions
- 900 issued patents
- 945 option/license agreements
- 98 new startups
- $120 million in revenues reinvested
- $1 billion in follow-on funding
- More than 1,000 direct jobs and many more indirect jobs

U-M Mentor Team

Numerous Partnerships

- ECONOMIC
  - Work closely with Ann Arbor SPARK, regional economic development partner, which provides microloans and pre-seed funding to startups
- STUDENT ENTREPRENEURSHIP
  - Our Tech Transfer Office does case studies and mentoring support for student entrepreneurs
- UNIVERSITY-LED COLLABORATIONS
  - Attract venture capital
  - Partner with industry

U-M Venture Center

- In-house business hub for entrepreneurs and startups
- Helped launch a new startup every five weeks on average
- Mentors-in-Residence program
- Gap funding
- Venture Accelerator: in-house incubator, houses 19 startups and provides lab & office space nearby
- U-M also an I-Corps Node for NSF

Need to "Sell" Tech Transfer

Tech Transfer Challenged Broadly

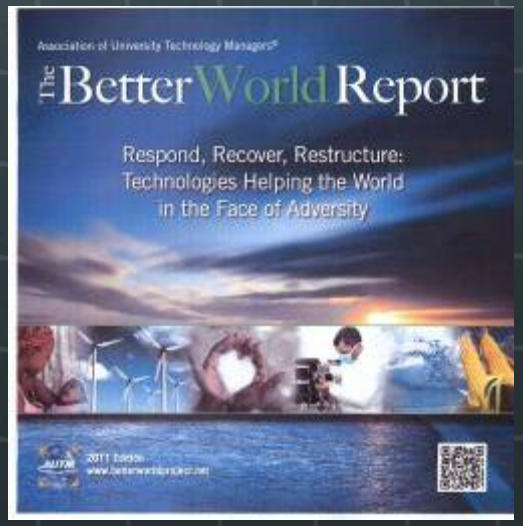
- New York Times article recently quoted from Brookings report that was totally off-base
- Other critics – Kauffman Foundation
- Senator Warner (D-VA) – tried to push StartUp Act that would allow faculty free agency of a sort
- Those involved in this process need to make sure public and policymaker education is a part of their daily activities

Telling our Story

- Many Members of Congress, others do not fully appreciate what the impact of our tech transfer is
- We send out lots of press releases when new companies are formed, but they get lost in the noise
- One key failing: we do not teach policymakers how the tech transfer process works
- That lack of understanding leads to bad legislation
- Also need to sell TT to our senior officials at universities

Making the Case

- Association of University Technology Managers (AUTM) trying to help
  - "Better World Report" highlights many of the amazing discoveries we have commercialized
  - New videos highlighting how that process works, also highlighting the impact individual inventions have had on the American public
  - Looking to become more pro-active in responding to critics



Policy Challenges

Congress Weighs In

- CONGRESS TAKES MAJOR STEP AT REWRITING PATENT LAW
  - AMERICA INVENTS ACT (2011)
    - First major rewrite of patent law since 1950s
    - First inventor to file
    - New procedures to contest patents within PTO
    - Goal was to "harmonize" US patent law with other nations
    - As with all legislation, some good parts – some not so good
      - Grace Period misdrafted – needs fixing or will deter faculty from writing, publishing research results

Patent Troll Issue

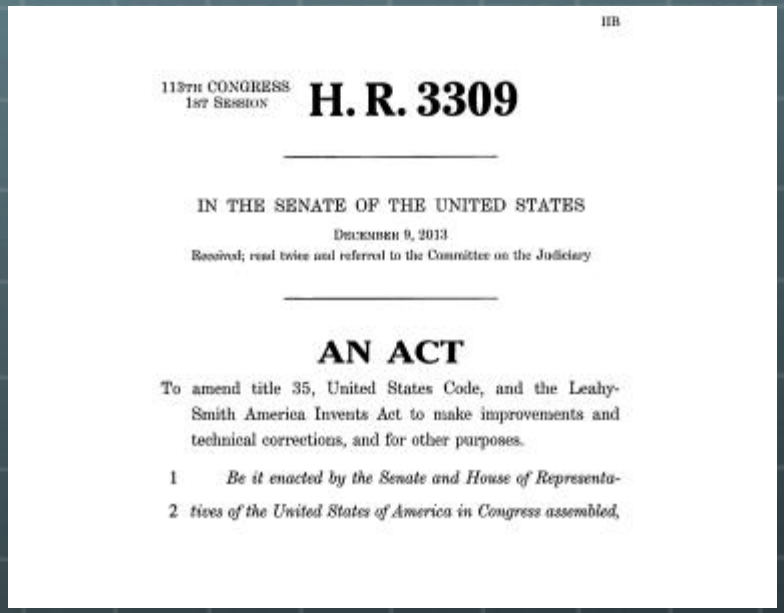
- Lastest effort to make changes to patent system, which could have a serious negative impact on ability to defend patents and to transfer technology
- Prompted by increase in so-called “demand letters” sent to small retailers, coffee shops, others
- “Shake downs” for alleged infringement
- Many businesses pay just to avoid hiring lawyer
- Abuse of patent system that needs to stop

The problem….

- In zeal to get trolls, legislation goes far beyond to erect new financial barriers to asserting patent infringement
- House bill (HR 3309) would require losers in litigation to pay legal fees for winners, unless judge finds loser's case completely meritorius
- Joinder provision also included --- could reach back to university for a patent it licensed – if startup were to sue and lose, university could be on hook
- Bill has other shortcomings

HR 3309 Approved

- Higher ed community tried numerous times to amend bill as it worked through system
- In November, House Judiciary Committee approved it
- Two weeks later, full House okayed it
- Senate Judiciary Committee took up its own version in mid-December



IIB

113TH CONGRESS
1ST SESSION

H. R. 3309

IN THE SENATE OF THE UNITED STATES

DECEMBER 9, 2013

Received; read twice and referred to the Committee on the Judiciary

AN ACT

To amend title 35, United States Code, and the Leahy-Smith America Invents Act to make improvements and technical corrections, and for other purposes.

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

Leahy Legislation

- S 1720 much better bill
- Much more focused on demand letters
- Did not include fee shifting/joinder
- However, other senators want to include bad provisions in ultimate Senate bill
  - Cornyn bill would add fee shifting/joinder
  - Hatch bill would require bond be posted
  - Schumer bill would greatly expand and make permament yet another PTO procedure for “business method patents”

December Hearing

- Six Democratic senators raise concerns
- Urge slowing down of process, thoughtful deliberation
- January/February – four Senate staff briefings held to educate all 100 offices about the issues at hand
- Now, negotiations are underway to try and reach a consensus
- Higher ed urging that this be done right

Administration More Involved

- **Major supporter of AIA**
- **But President says AIA only went so far**

*"… I do think that our efforts at patent reform only went **about halfway** to where we need to go and what we need to do is pull together additional stakeholders and see if we can build some additional consensus on smarter patent laws."*

White House Active

- President announces major regulatory effort at PTO to squelch troll activities
- White House endorses Goodlatte bill in House on patent trolls
- Continuing to play a role – hosted recent White House roundtable on patent issues

White House Active

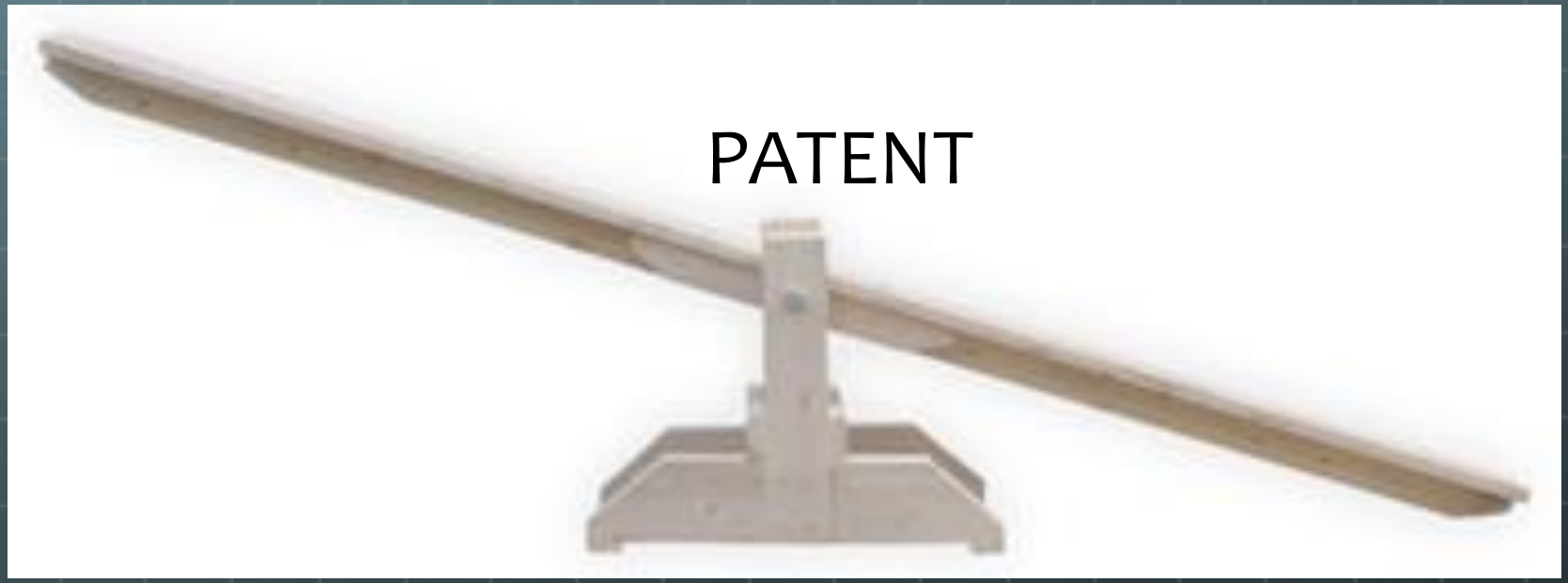
- Strong supporter of troll legislation
- Unclear how wedded it is to particular pieces of bills
- We have tried to engage them – drawn contrast between desire for more commercialization but at the same time making patent assertion tougher
- Commerce Department was very engaged in first Obama term on NACIE effort to encourage more commercialization

Judiciary Responding

- Part of motivation for legislation is concern that federal judges don't use discretion they have now to shift fees and deter bad behavior
- Chief Judge of Federal Circuit Rader working hard to get his judges to be more aggressive and take this on

Patent is the KEY

INVENTION



COMMERCIALIZATION

Outlook

- Continued challenges by various entities to patent system into the foreseeable future
- Tech transfer offices and universities need to stay on their toes and be pro-active in making the case
- Educating policymakers is vital
- Working collaboratively with higher ed association, industry partners, others also key to success

Description of Problematic Provisions

- **<u>Fee shifting (loser pays) (S. 1013, S. 1612)</u>:** refers to situations where the nonprevailing party pays the costs of the prevailing party
    - Significantly increases financial risk of asserting patents for universities – non-profit institutions lacking large litigation budgets
    - S. 1013, Cornyn: fee shifting does not occur if non-prevailing party's actions are "objectively reasonable and substantially justified"; seems like a reasonable threshold for requiring the loser to have to pay the winners costs; however –
        - Burden always on nonprevailing party to justify its conduct
        - Experience of the government under the Equal Access to Justice Act, after which S. 1013 fee shifting modeled, indicates that fee shifting is far from a rare occurrence
        - Thus, significant risk of university being subjected to loser pays under the proposed fee-shifting provisions; the prospect of paying court costs and attorney fees for both parties a powerful disincentive for universities to enforce their patents
    - Supreme Court has agreed to review two patent infringement cases concerning award of attorney fees (*Octane* and *Highmark*), oral arguments Feb 26, decision before July 4, Given the potential impact of a sweeping fee-shifting provision on universities, start-ups, small business, and independent inventors, Congress should wait for these court cases to play out before legislating on fee shifting
- **<u>Joinder (S. 1013)</u>:** – involves a court granting a defense motion to bring into the case as a co-plaintiff anyone who has an ownership interest in or other functional connection to the patent – under this provision, a university could be brought into a case *over which it has had no control* and become a nonprevailing plaintiff subject to fee shifting
    - The scope of joinder proposal in S. 1013 is extremely broad, covering *any* civil action arising under *any* Act of Congress relating to patents, which sweeps in at

least 21 statutes, could apply to issues such as contract disputes having nothing to do with trolls

  - An apparent protection against unwarranted joinder requires defendant to show that the interest of the plaintiff is limited primarily to asserting the patent or a given patent claim in litigation. The intention of this provision is laudable, seeking to target trolls, but the protection is much less robust than it may seem – a number of ways that a legitimate patent holder could be could be inappropriately cast as a troll, causing joinder of an uninvolved party such as a university

- The <u>combination of fee shifting and joinder</u> is especially troubling to universities; we are very concerned that they could seriously damage the university technology transfer process by increasing the financial risk to universities and their licensees enforcing their patents and by discouraging potential licensees and venture capitalists from investing in the development of promising discoveries resulting from university research; such consequences would move in the opposite direction of ongoing university/industry/government efforts to expand breadth and pace of commercialization of inventions resulting from university research
- **<u>Limitations on discovery (S. 1013)</u>:** – limits discovery able to be carried out before claims construction, would make it more difficult to provide information called for in heightened pleading, militate against cases where broader discovery would be more efficient, overrides judicial discretion to limit discovery on case-by-case basis
- **<u>Heightened Pleading (S. 1013)</u>:** calls for excessive information to be presented when a patent infringement case filed; some information may not be available when needed due to proposed limitations on discovery
- **<u>Increased transparency (S. 1720)</u>:** calls again for excessive information that must be updated for the life of the patent, requires disclosures that would violate confidentiality agreements, chill VC investments
- **<u>Expanded covered business method patent program (S. 866)</u>:** expands in two ways a narrowly crafted AIA eight-year program to challenge the validity of a narrow category

of business method patents – 1) by making the temporary AIA program permanent, and 2) expanding the scope of patents covered beyond business methods to include any patents involving data processing methods, sweeping in biotechnology, software and other patents, increasing patent uncertainty, reducing the incentive for early challenges to patents, and upsetting the careful balance between post grant and inter partes review codified in the AIA

- **Customer stays (S. 1720):** intended to protect customers and other retain end users who use but do not manufacture patented products; the breadth of the proposals would allow collusion among parties along the supply chain, immunizing parties from charges of infringement and weakening the ability to assert patent rights
- **Demand letters (S. 1720):** intended to target bad faith demand letters often sent out in large numbers charging infringement or making fraudulent charges, but provisions written so broadly that they could implicate legitimate and necessary communications on patent licensing and other transactions
- Getting this right critical for the nation's innovative capacity and economic competitiveness – particularly important in the face of rapidly increasing international competition

CPIP-WARF Conference - GMU
21 March 2014

UNIVERSITY TECHNOLOGY TRANSFER AND THE PATENT SYSTEM

Dr. Stuart Graham
Georgia Tech

Georgia Tech Ernest Scheller Jr. College of Business

Public R&D Sources, reported importance to industry R&D

Information source	% rating it as "very" or "moderately" important for industrial R&D
Publications & reports	41.2%
Informal Interaction	35.6
Meetings & conferences	35.1
Consulting	31.8
Contract research	20.9
Recent hires	19.6
Cooperative R&D projects	17.9
Patents	17.5
Licenses	9.5
Personnel exchange	5.8

From Cohen, W. et al (2002) “Links and Impacts: The Influence of Public Research on Industrial R&D,” *Management Science,* vol. 48.

Table 4 Importance to Industrial R&D of Information Sources on Public Research

Industry	N	Patents	Pubs./ Reps.	Meetings or Conferences	Informal Interaction	Recent Hires	Licenses	Coop./ JV's	Contract Research	Consulting	Personnel Exchange
					Percentage of Respondents Indicating Research "Moderately" or "Very" Important						
2320: Petroleum	18	0.0	38.9	50.0	27.8	11.1	11.1	11.1	22.2	44.4	0.0
2400: Chemicals, nec	73	24.7	35.6	28.8	20.6	16.4	8.2	15.1	20.8	24.7	9.6
2411: Basic chemicals	41	17.1	36.6	26.8	39.0	17.1	2.4	14.6	17.1	34.2	2.4
2413: Plastic resins	28	14.3	35.7	32.1	21.4	21.4	0.0	3.6	10.7	14.3	0.0
2423: Drugs	68	50.0	73.5	64.7	58.8	30.9	33.8	41.2	52.9	58.8	8.8
2429: Miscellaneous chemicals	32	25.0	34.4	25.0	31.3	21.9	3.1	3.1	12.5	25.0	0.0
2500: Rubber/plastic	35	5.7	17.1	14.3	11.4	14.3	2.9	11.4	8.6	22.9	0.0
2610: Glass	6	33.3	50.0	50.0	50.0	50.0	16.7	50.0	33.3	33.3	0.0
2695: Concrete, cement, lime	10	30.0	50.0	30.0	20.0	30.0	30.0	10.0	10.0	10.0	10.0
2700: Metal, nec	8	25.0	62.5	62.5	87.5	25.0	0.0	25.0	37.5	50.0	12.5
2710: Steel	11	18.2	36.4	54.6	45.5	18.2	18.2	36.4	54.6	36.4	18.2
2800: Metal products	51	19.6	25.5	13.7	25.5	17.7	7.8	13.7	9.8	21.6	3.9
2910: General purpose machinery, nec	76	15.8	30.7	26.3	30.3	14.5	7.9	10.5	13.2	31.6	1.3
2920: Special purpose machinery, nec	72	19.4	33.3	33.3	27.8	16.7	11.1	16.7	15.3	30.6	2.8
2922: Machine tools	11	9.1	36.4	45.5	45.5	18.2	0.0	9.1	18.2	36.4	0.0
3010: Computers	29	13.8	41.4	37.9	34.5	34.5	3.5	6.9	6.9	24.1	3.5
3100: Electrical equipment	23	8.7	30.4	21.7	21.7	0.0	0.0	8.7	13.0	8.7	0.0
3110: Motor/generator	25	4.0	40.0	36.0	44.0	12.0	0.0	20.0	12.0	28.0	4.0
3210: Electronic components	27	18.5	37.0	33.3	33.3	29.6	11.1	14.8	11.1	30.8	3.7
3211: Semiconductors and related equipment	25	20.0	60.0	48.0	54.2	36.0	12.0	20.0	20.0	40.0	4.0
3220: Comm equipment	37	5.4	48.7	32.4	32.4	27.0	8.1	8.1	16.2	29.7	18.9
3230: TV/radio	9	22.2	66.7	33.3	33.3	33.3	11.1	33.3	22.2	22.2	11.1
3311: Medical equipment	74	27.0	40.5	36.5	47.3	18.9	17.6	23.0	23.0	44.6	6.8
3312: Precision instruments	39	23.1	46.2	41.0	41.0	10.3	12.8	18.0	7.7	33.3	5.1
3314: Search/navigational equipment	40	7.5	52.5	50.0	50.0	20.0	12.5	27.5	32.5	42.5	12.5
All	1,229	17.5	41.2	35.1	35.6	19.6	9.5	17.9	20.9	31.8	5.8

From Cohen, W. et al (2002) "Links and Impacts: The Influence of Public Research on Industrial R&D," *Management Science,* vol. 48.

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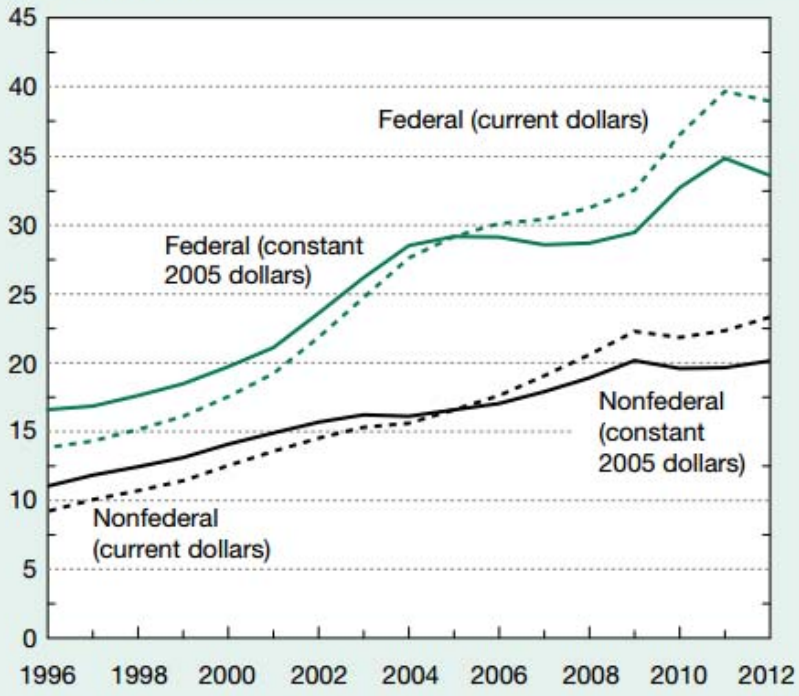
3211: Semiconductors and related equipment	25	20.0	60.0	36.0	12.0
3220: Comm equipment	37	5.4	48.7	27.0	8.1
3230: TV/radio	9	22.2	66.7	33.3	11.1
3311: Medical equipment	74	27.0	40.5	18.9	17.6
3312: Precision instruments	39	23.1	46.2	10.3	12.8

From Cohen, W. et al (2002) “Links and Impacts: The Influence of Public Research on Industrial R&D,” *Management Science,* vol. 48.

Figure 5-1
Federal and nonfederal academic S&E R&D expenditures: FYs 1996–2012

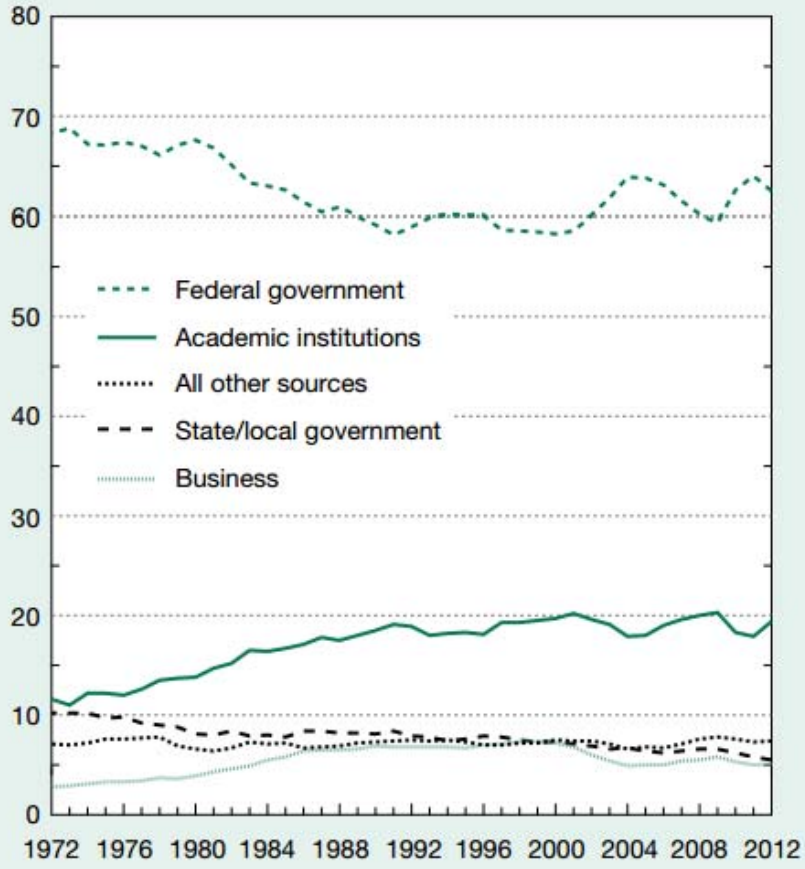


NOTES: Data include expenditures for S&E R&D. Gross domestic product implicit price deflators were used to convert current dollars to constant 2005 dollars.

SOURCE: National Science Foundation, National Center for Science and Engineering Statistics, Higher Education Research and Development Survey. See appendix table 5-2.

Science and Engineering Indicators 2014

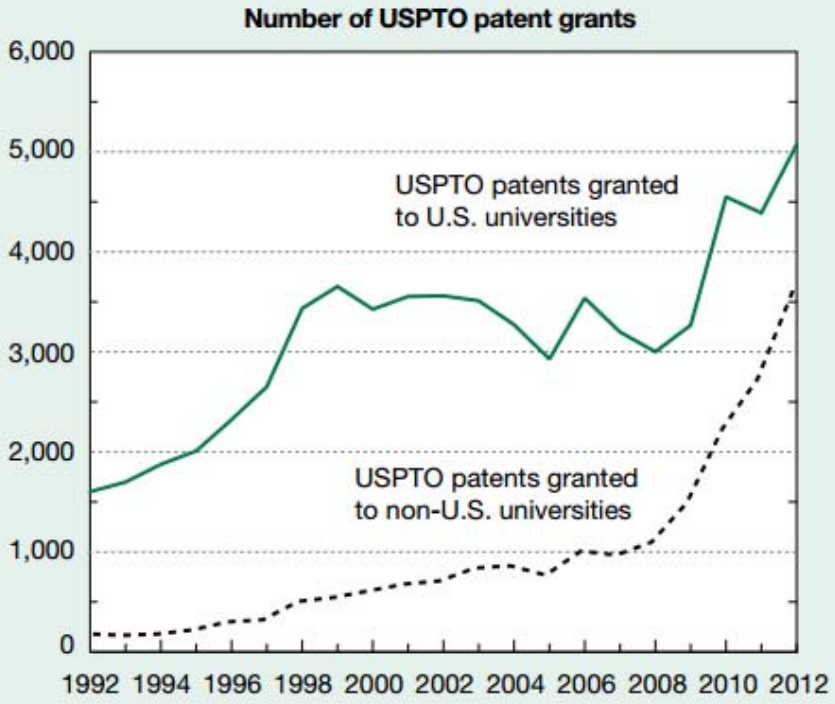
Figure 5-2
Academic S&E R&D expenditures, by source of funding: FYs 1972–2012

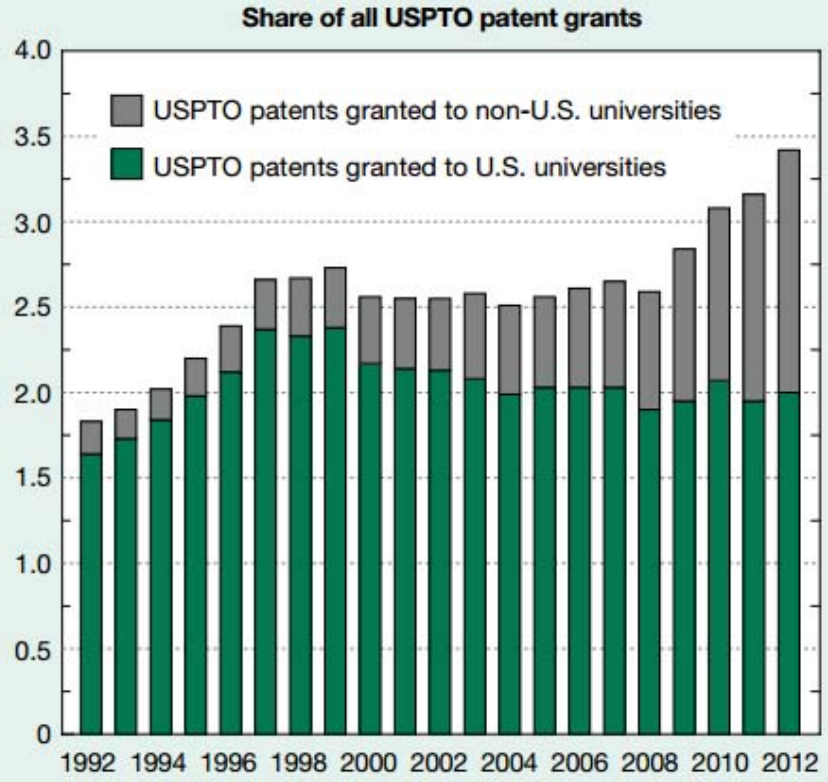


SOURCE: National Science Foundation, National Center for Science and Engineering Statistics, Higher Education Research and Development Survey.

Science and Engineering Indicators 2014

Figure 5-34
USPTO patents granted to U.S. and non-U.S. academic institutions: 1992–2012



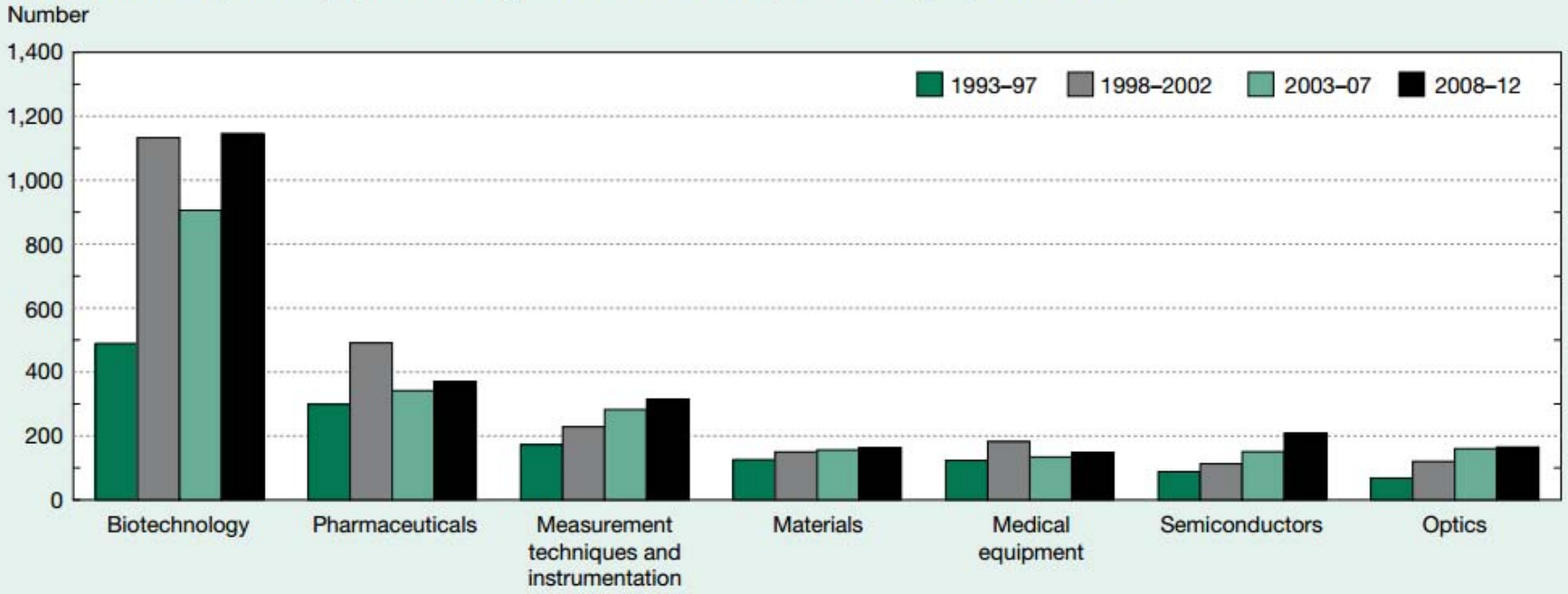


USPTO = U.S. Patent and Trademark Office.

SOURCE: The Patent Board,™ special tabulations (2013) of Proprietary Patent database. See appendix table 5-62.

Science and Engineering Indicators 2014

Figure 5-36
U.S. academic patents, by technology area: Selected 5-year averages, 1993–2012

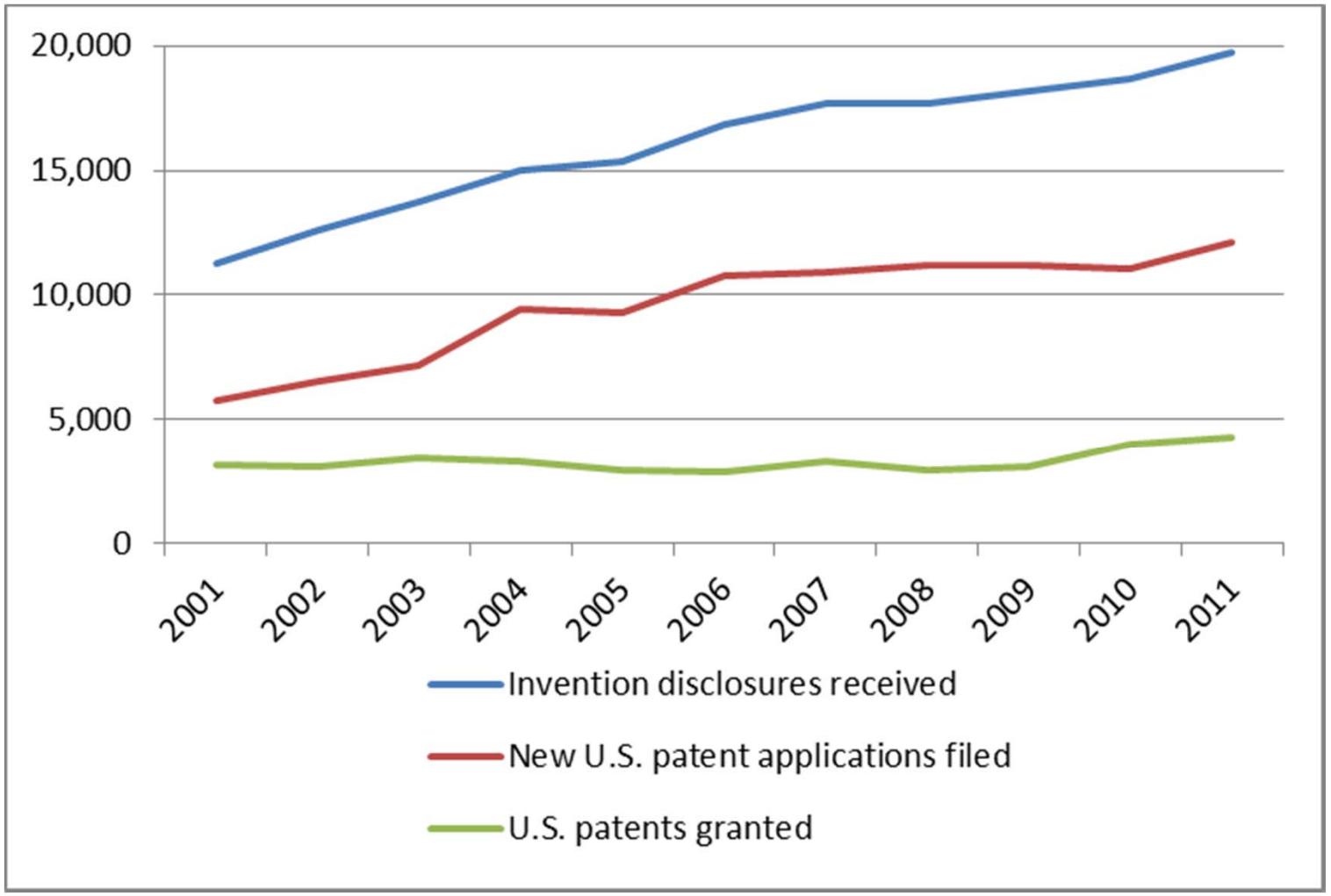


NOTES: Data include institutions affiliated with academic institutions (e.g., university and alumni organizations, foundations, and university associations). Universities vary in how patents are assigned (e.g., to boards of regents, individual campuses, or entities with or without affiliation with the university). The Patent Board™ technology areas constitute an application-oriented classification system that maps the thousands of International Patent Classes (IPCs) at the main group level into 1 of 35 technology areas. If a patent has more than one IPC, only the primary IPC is considered in mapping.

SOURCES: National Science Foundation, National Center for Science and Engineering Statistics, and The Patent Board,™ special tabulations (2013) from U.S. Patent and Trademark Office (USPTO), Patent Grant Bibliographic Data. See appendix table 5-63.

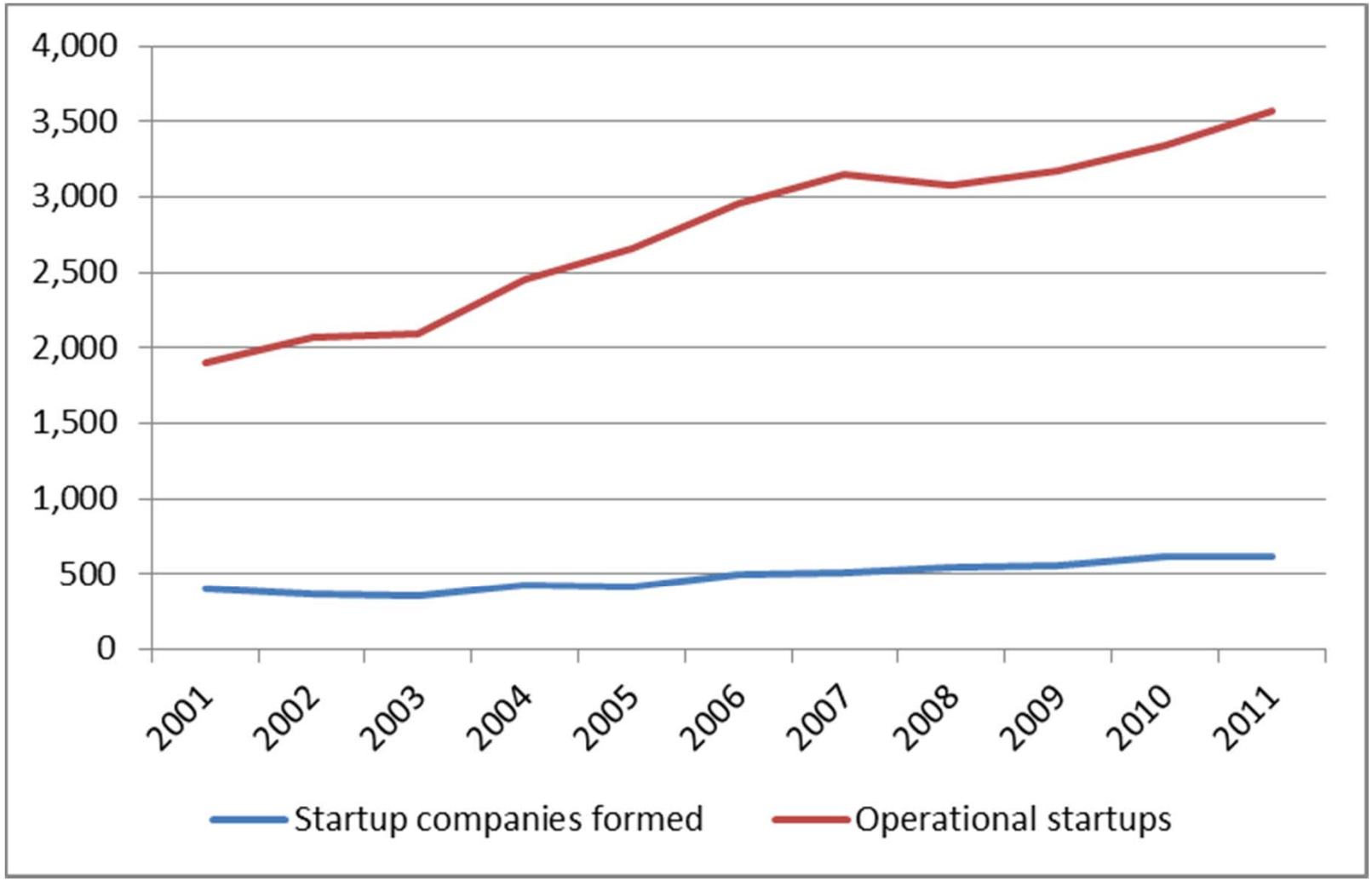
Science and Engineering Indicators 2014

Academic patenting, 2001-2011



SOURCE: Association of University Technology Managers (AUTM), AUTM Licensing Survey (various years).
NAS Science and Engineering Indicators 2014

University Startup Companies, 2001-2011



SOURCE: Association of University Technology Managers (AUTM), AUTM Licensing Survey (various years).
NAS Science and Engineering Indicators 2014

HIGH TECHNOLOGY ENTREPRENEURS AND THE PATENT SYSTEM: RESULTS OF THE 2008 BERKELEY PATENT SURVEY

Stuart J.H. Graham,[†] Robert P. Merges,[††] Pam Samuelson,[†††] & Ted Sichelman[††††]

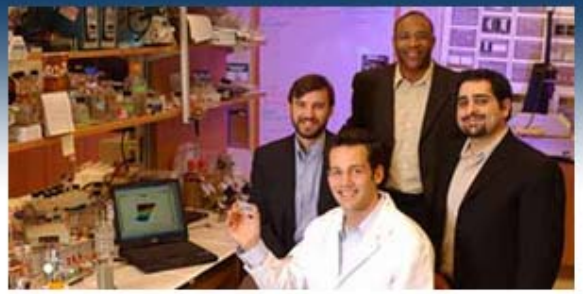
ABSTRACT

We offer description and analysis of the 2008 Berkeley Patent Survey—the first comprehensive survey of patenting and entrepreneurship in the United States—summarizing the responses of 1,332 early-stage technology companies founded since 1998. Our results show that entrepreneurs have varied and subtle reasons for using the patent system, many of which diverge from the traditional theory that patents provide an "incentive to invent." Somewhat surprisingly, startup executives report that patents generally provide relatively weak incentives to conduct innovative activities. But while a substantial share of early-stage companies hold no patents, we also find that holding patents is more widespread than previously reported, with patenting patterns and motives being highly industry, technology, and context specific.

Georgia Tech ti:ger
Technological Innovation: Generating Economic Results

An Innovative Curriculum at the Intersection of Science, Business and Law

Contact Us



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LAUNCHING AND BUILDING TECHNOLOGY COMPANIES

Georgia Tech's Advanced Technology Development Center is a Startup Powerhouse

When he enrolled as a Ph.D. student in Georgia Tech's College of Computing five years ago, Vijay Balasubramaniyan never expected to become the CEO of one of Atlanta's hottest young information security companies.

Since 1986, ATDC companies attracted MORE THAN $2 billion IN OUTSIDE CAPITAL

Since 1987, ATDC's 150 graduate companies have generated MORE THAN $12 billion IN REVENUE

ATDC by the numbers

In 2013, ATDC companies created a combined total of MORE THAN $1 billion IN REVENUE

In 2013, ATDC companies attracted MORE THAN $50 million IN OUTSIDE CAPITAL

Thank you

graham@gatech.edu

University IP as a Driver of Economic Development

From Lab to Market

CPIP, George Mason Univ.

March 21, 2014

Sean M. O'Connor, Esq.
Professor of Law
Chair, UW IP Management Advisory Committee
University of Washington, Seattle, WA

SCHOOL OF LAW
UNIVERSITY of WASHINGTON
Law, Technology & Arts Group

University of Washington Tech Transfer Ecosystem

- External: Washington Research Foundation
- Internal: Office of Technology Transfer
- OTT renamed Center for Commercialization (C4C)
- Reflects shift of focus from traditional licensing function to start-ups/spin-outs
- Record 17 spin-outs in FY13

University of Washington Tech Transfer Ecosystem

- Use of law and business students to assist commercialization and spin-offs; Entrepreneurial Law Clinic; "venture associates"
- W Fund and other gap funding
- Low or no cost knowledge/technology dissemination also important
- Faculty inventor issues in wake of *Stanford v. Roche*
- Complications of grants, contracts, and "other" funding agreements

SCHOOL OF LAW
UNIVERSITY of WASHINGTON
Law, Technology & Arts Group

Quintessence | Biosciences

A Cancer Drug Development Company

Laura Strong, PhD

President and COO

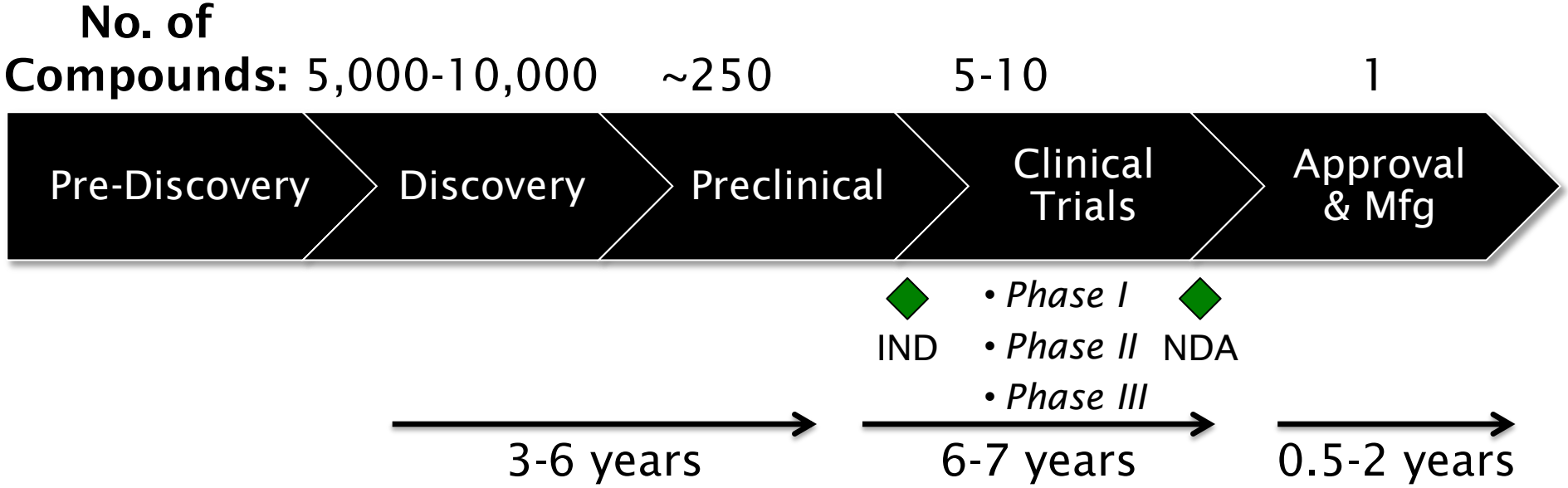
Additional experiences include:

Economic Development Commission

Board of Advisors

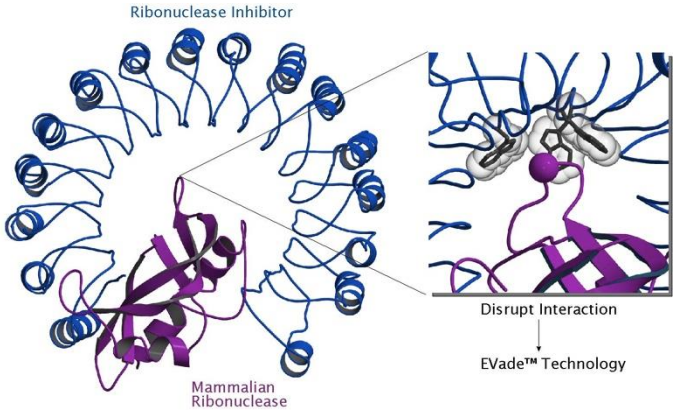
Launching a Biotech Company

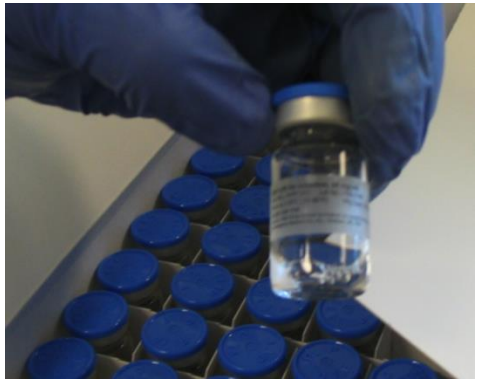
- In 2000, licensed five UW-Madison technologies from WARF
- Developed focus on cancer therapies



Inventions & Innovation

Invention	Innovation
Research	Development
Idea	Product





Quintessence | Biosciences

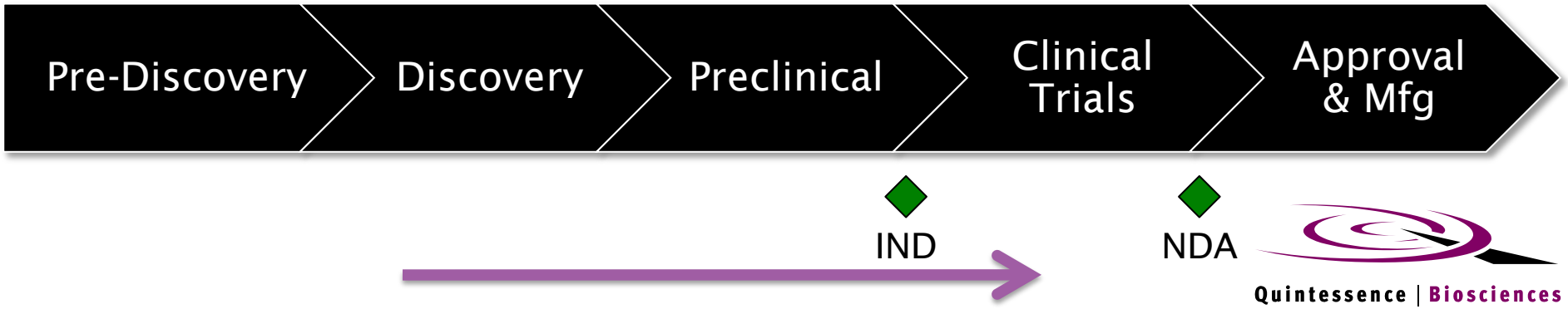
Raines Lab @ UW-Madison: Invention

- Discovery that human ribonucleases can be engineered to kill cancer cells
- Demonstration in cell culture

Quintessence | Biosciences

QuintBio: Innovation

- More than forty compounds made & tested in cell culture and in *in vivo* models
- One selected for preclinical toxicology studies and IND
- Developed and scaled manufacturing process, including cGMP process
- Phase I human clinical trial



Economic Impact of Our Technology Transfer

- Capital
  - ~$18M in equity financing, primarily Wisconsin investors
  - ~$1.5M in federal Small Business Innovation Research (SBIR) grants
- Employment
  - Wisconsin: Max of 11 employees at one point, primarily scientists with advanced degrees
    - Battelle reported a biopharma multiplier of ~3*
  - US: Various consulting/contracting arrangements
    - Example: Althea Technologies for manufacturing drug
- Infrastructure
  - Long term tenant at University Research Park in Madison
  - Equipment and supplies for small scale manufacturing, characterization, cell culture, etc.

*The Economic Impact of the US Biopharmaceutical Industry, July 2013

Potential Issues when Partnering with Tech Transfer Offices

- Cultural differences, including relative importance of time and money
- Mismatch in perceived value of
  - Original invention
  - Invention vs. development capabilities of company/entrepreneur
- Even if TTO has equity, different stakeholders than traditional equity investors

Panel 2 *Recent and Proposed Patent Legislation's Impact on Bringing R&D to Market*

- Earl "Eb" Bright, *Executive Vice President and General Counsel*, ExploraMed
- Carl Gulbrandsen, *Managing Director*, Wisconsin Alumni Research Foundation
- Greg Raleigh, *CEO and Chairman*, ItsOn
- Rob Sterne, *Director*, Sterne, Kessler, Goldstein & Fox
- *Moderator*: Kevin Noonan, *Partner*, McDonnell Boehnen Hulbert & Berghoff LLP

#LabtoMarketIP

Recent and Proposed Patent Law Legislation's Impact on Bringing R&D to Market

CPIP& WARF IP Conference

George Mason University Law School

March 21, 2014

Moderator: Kevin E. Noonan, Ph.D.

McDonnell Boehnen Hulbert & Berghoff LLP

(Leahy-Smith) America Invents Act

- Enacted to “simplify” U.S. patent law and harmonize with ROW
- Purported benefits
  - Simpler
  - Priority determinations more certain
  - Prior user rights makes patent/no patent decision easier
  - Provides numerous ways to challenge/remedy “bad” patents
    - Inter partes review
    - Covered business methods review
    - Post-grant review

“Bad” patents

- Reexaminations provided for two reasons
  - Reduce need to incur litigation costs
  - To provide way to invalidate “bad” patents
- Ex parte review relied on first rationale
- All these others rely on second rationale
- But whether a patent is bad depends
  - It does not comply with the statute
  - It belongs to a competitor
  - You have been sued on it
  - You don’t think the subject matter should be patented

Four Ways for PTO Review

- *Ex Parte* Reexamination (old)
- Supplemental Examination (new)
  - Effective September 16, 2012
- Post-Grant Review (new)
  - Effective September 16, 2012 to "3(n)(1) patents"
    - Only patents with priority dates after March 16, 2013
- *Inter Partes* Review (new/old)
  - Effective September 16, 2012 to all pending patents

Post-Grant Review

- Must be filed within 9 months of grant (post-AIA)
- Much broader review than any previous options
  - Printed publications
  - On sale/public use
  - § 112 issues
  - § 101 issues
- Lower burden of proof
  - Preponderance/No Presumption of Validity
- Threshold: "more likely than not that at least one of the claims challenged is unpatentable"

Post-Grant Review

- Litigation estoppel: Petitioners may not assert issues that they "raised or reasonably could have raised"
  - E.g., obviousness-type double patenting in PGR
- No estoppel unless final written decision on the merits
  - Estoppel avoided by settlement
- Director to set regulations for time limits of no longer than 1 year or 18 months
- Appeal only to the CAFC

Inter Partes Review

- *Inter Partes* Review
  - Limited to §§ 102 and 103 on the basis of patents/applications and printed publications
  - New Threshold: Granted if "reasonable likelihood that the petitioner would prevail with respect to at least one of the claims"
    - Changed from substantial new question of patentability

Inter Partes Review

- Can be terminated by settlement prior to decision
- Litigation estoppel: Petitioners may not assert issues that they "raised or reasonably could have raised"
- Applies to all patents one year after enactment
- Appeal only to the CAFC

Major drawbacks

- Uncertainty the major disadvantage of the reviews
- Post-grant review delays when patent is licensed
- *Inter partes* review always available, stand alone or as part of a litigation strategy
- No repose – patent is always capable of being challenged
- PTO provides easier route for invalidation (preponderance vs. “clear and convincing”; PTO claim construction standard (broadest reasonable interpretation)

Innovation Act

- One bill passed in the House (H.R. 3309); several bills pending in Senate (S.1720 = H.R.3309)
- Purported motivation: patent “troll” problem
- Problem: “troll” = non-practicing entity = university
- Why now? “great” increase in troll litigation (number of filed cases)
- But, not a real basis because an artifact of AIA changes in pleading standards so multiple defendants cannot as readily be named, so number of filed cases has increased

Provisions

- Fee-shifting, to enhance the ability for district courts to award attorneys' fees and costs to prevailing defendants by making these payments the default rather than the exception (also, joinder)
- Real-party-in-interest (assignee, exclusive licensee) required to be identified, for all granted patents, and updated expeditiously – patent forfeiture as penalty (statutory support?)
- Heightened pleadings requirements, supporting infringement and willful infringement

Panel

- **Rob Sterne**: expectations of the various post-grant review provisions, and how these items are already playing out
- **Carl Gulbrandsen**: the large research university perspective, relating to changes in prior art definitions (including confusion about the grace period) and state level efforts to impose additional burdens on patent holders (patent notification legislation)
- Also the effects of “anti-troll” legislation on universities and other NPEs

Panel

- **Eb Bright**: the medical device company perspective, including effects of uncertainty caused by AIA and Innovation Act on fund raising. Investment aspects
- **Greg Raleigh**: the IT company perspective as experienced by a serial entrepreneur, including the impact of post-grant review on valuation of start-ups trying to find investors
- The panel will also discuss modifications to current proposals and alternatives to proposed legislation

Questions

- Why do you think we are hearing so much lately about patent trolls and other bad actors and patents as obstacles to innovation? Are there ways to address the perception that the system is flawed without adversely impacting the majority of users of the patent system? How do we address problems or shortcomings of the patent system without providing support to those who are trying to weaken rather than improve the system?

Questions

- Speaking of bad actors, listening to the current dialog on patents, it is tempting to think that all of the abuse is being perpetrated by patent holders. Is that your experience? Are there ways in which patent holders actually keep a check on unfair practices that hamper the process of bringing new ideas to the marketplace? To what extent are the patent holders (particularly smaller players who rely on licensing) responding to intransigence by potential licensees?

Questions

- State initiatives focused on heightened patent notification requirements have been enacted or are proposed in many states. Is there a federal approach to this issue that makes more sense? Are there examples in other areas of law making where this combination of a federal and state legal framework has made sense? In view of Federal preemption in the area of patent law, would these laws be enforceable?

Earl "Eb" Bright, JD/MBA
Chief Operating Officer, Arisa Health
Executive Vice President, ExploraMed Development, LLC

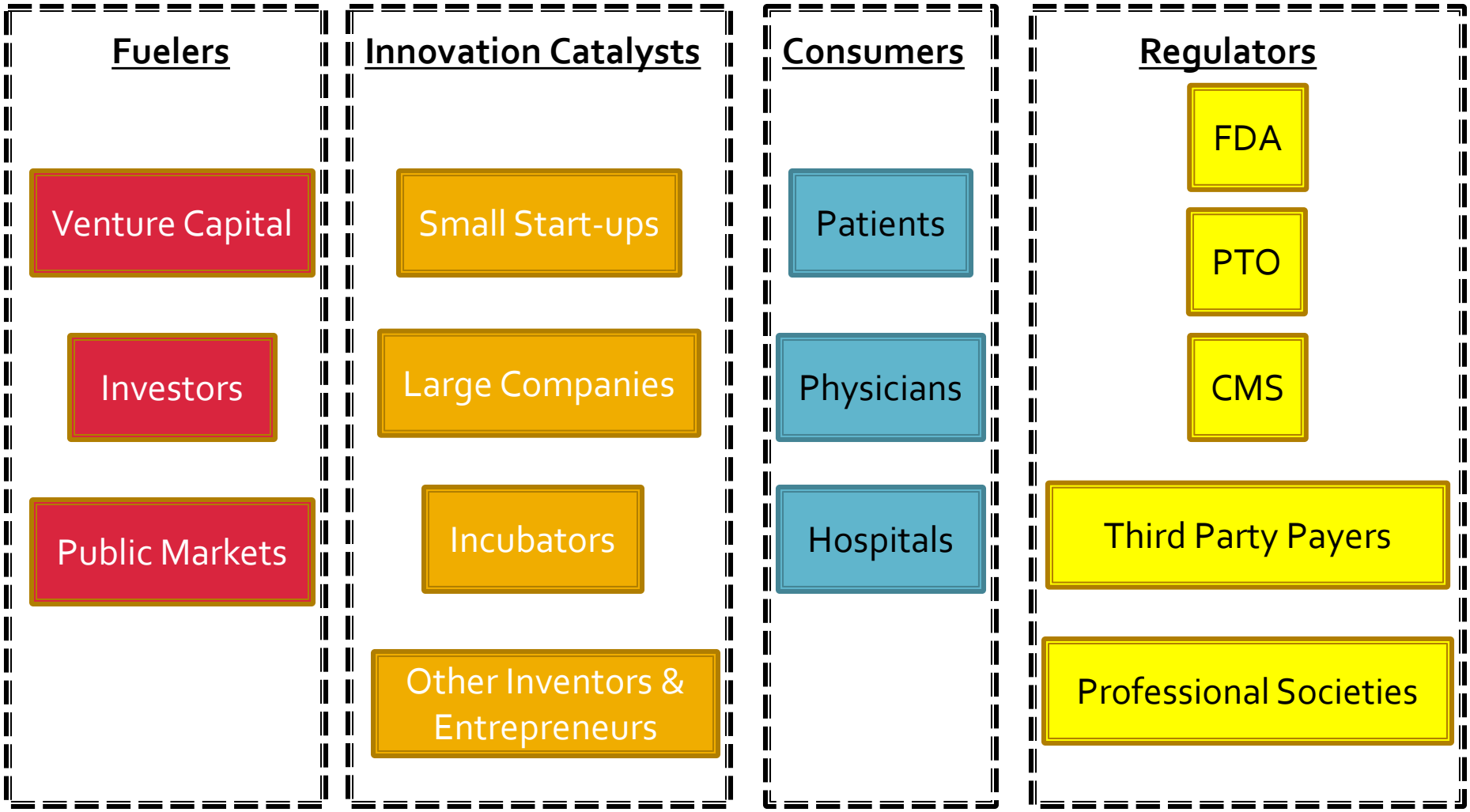
Brief Overview of the MedTech Innovation Ecosystem

Innovation Is Important To Patients

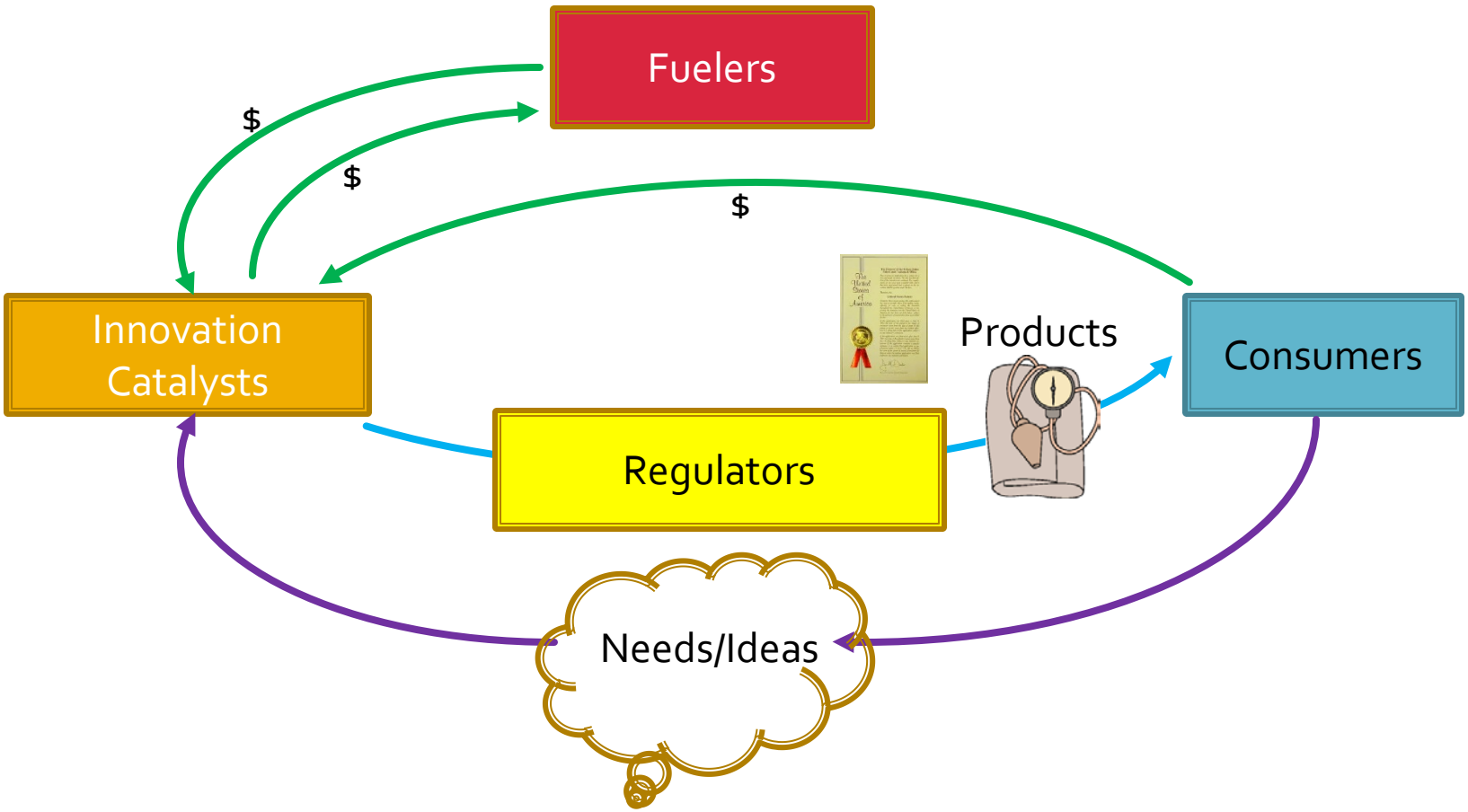
- Pain, suffering and death from disease still plague patients worldwide
- Even where solutions exist, many remain non-optimal
- Fortunately, our US economic system has created the incentives and the resources to promote and reward innovation to help patients…

  … this has created a true *MedTech Innovation Ecosystem*

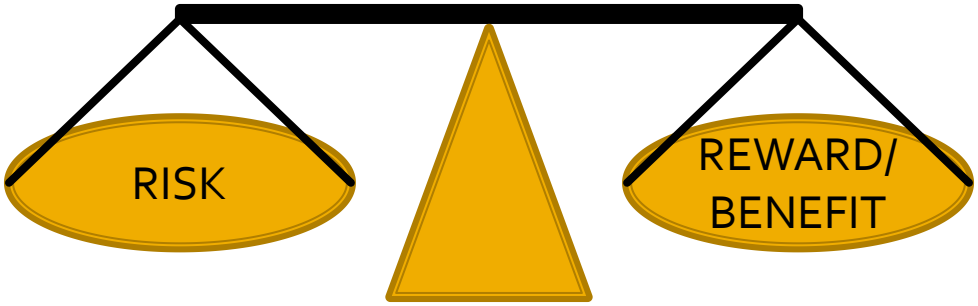
Parts Of The MedTech Innovation Ecosystem



MedTech Innovation Ecosystem



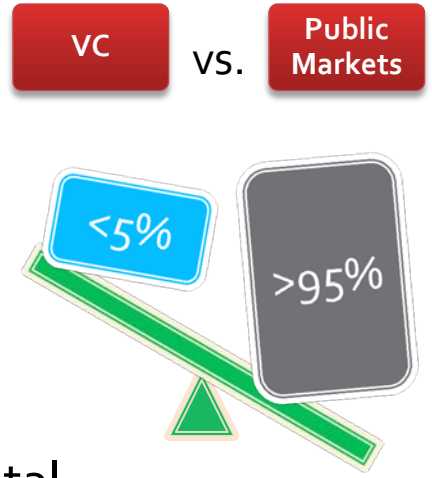
All Decision Makers In The Ecosystem Seek To Optimize Risk/Benefit Balance



- Fuelers
  - Financial Risk / Return
- Innovators
  - Financial Risk / Return
  - Clinical Safety / Benefit
  - Enterprise Failure / Survival
- Consumers
  - Clinical Safety / Benefit
  - Financial Cost / Benefit
- Regulators
  - Clinical Safety / Benefit
  - Claim Scope/Benefit
  - Financial Cost / Benefit

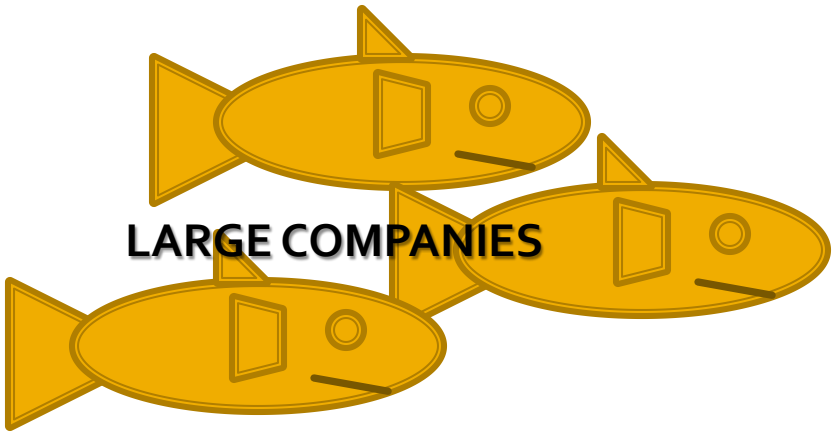
Investors Fuel Innovation Ecosystem, But They Have A *Fixed* Tolerance For Risk

- Investors
  - Fuel innovation **via venture capital**
  - Balance risk & return in a fixed way
  - Patents protect their investment
  - Typical allocation for institutional fund
    - Less than 5% of total is invested into Venture Capital
    - Less than 15% of the 5% is dedicated to MedTech

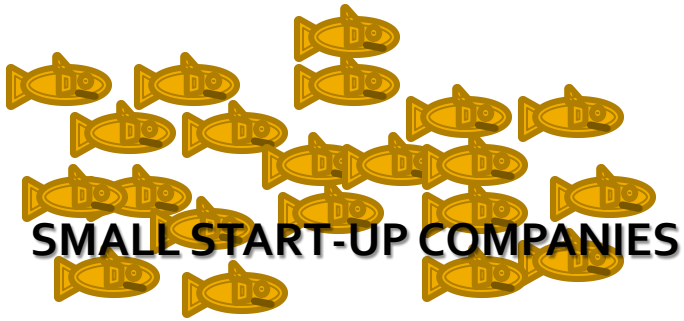


VC underperforms	→	VC commitments ↓
Public market underperforms	→	VC commitments ↓
		(fixed ratio VC/public investments)
Only when VC outperforms	→	VC commitments ↑

The Innovation Catalyst Ecosystem



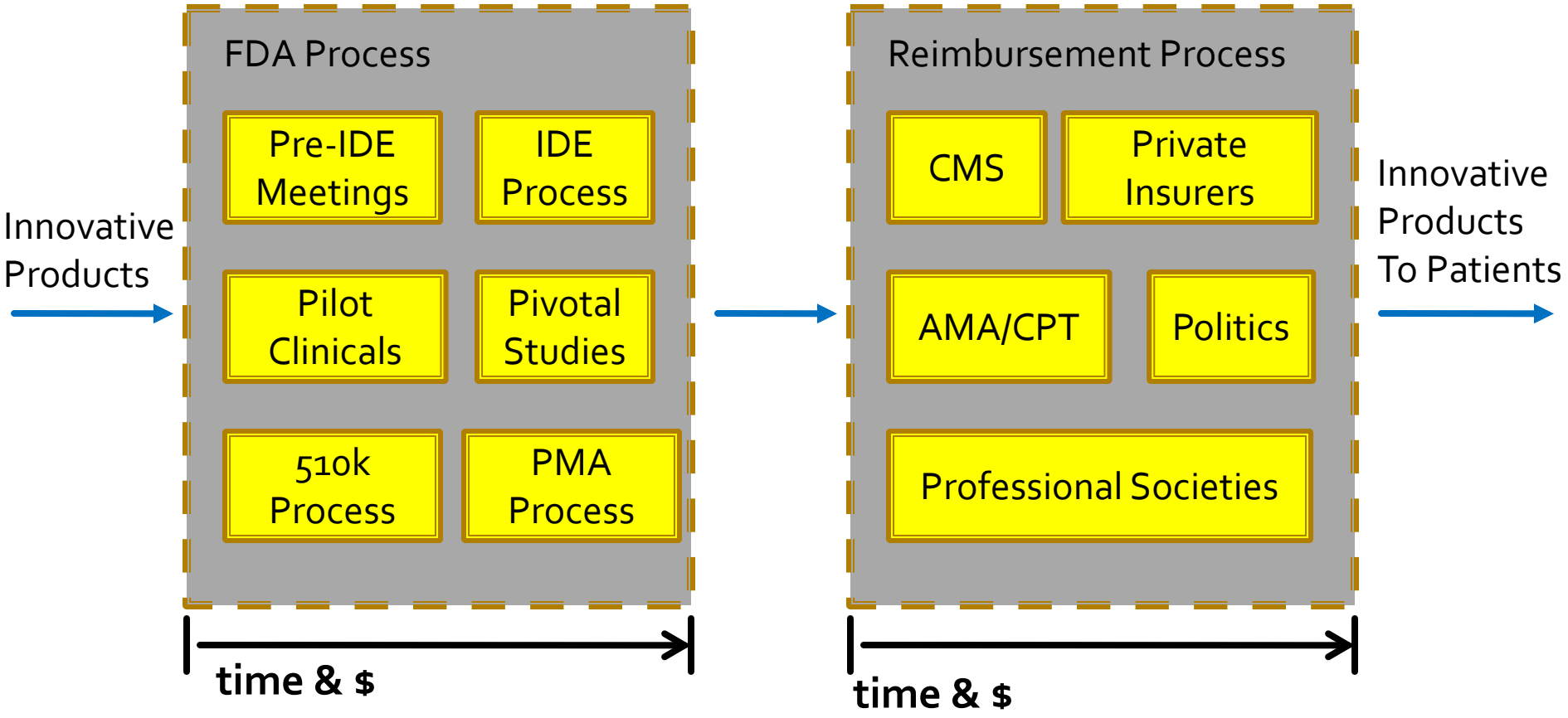
Large Companies:
Require a steady diet of new innovative small companies to ensure growth and scale delivery of solutions to patients
(Sensitive To Financial Markets & Availability Of Quality Start-Ups)



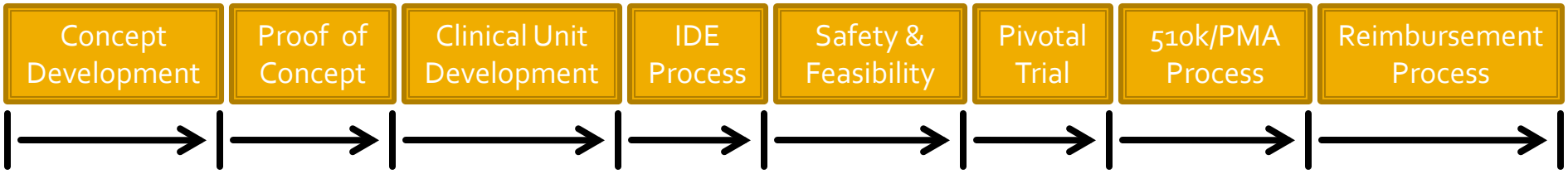
Small Start-Ups:
Require a steady diet of venture capital to fund innovations
(Sensitive To Restrictions of Capital Flow And Increases In Delays / Expenses / Costs)

Venture Capitalists:
Require a steady flow of positive returns to continue to provide flow of nutrients and ensure survival as an asset class
(Very Sensitive To Returns & Financial Markets)

Regulatory & Reimbursement Pathway



The Upfront Cost Of Bringing Safe & Effective MedTech Innovations To The Market



Typical Burn Rate	$233K/mo	$351K/mo	$650K/mo	$802K/mo	$949K/mo	$1.72M/mo	$1.35M/mo	$2M/mo
Target Timing (510k)	6 months	6 months	9 - 12 months	1 - 3 months	3 - 6 months	6 - 12 months	3 - 6 months	0 – 3 Years
Target Costs (510k)	$ 1.3MM	$ 2.1MM	$ 6.8MM	$ 1.6MM	$ 4.3MM	$ 15.5MM	$ 6.1MM	$ 36MM
Total (510k):		$ 3.4MM	$ 10.2MM	$ 11.8MM	$ 16.1MM	$ 31.6MM	$ 37.7MM	$ 73.7MM
Target Timing (PMA)	6 months	6 - 12 months	12 - 18 months	3 – 6 months	6 – 12 months	6 - 36 months	18 – 24 months	0 – 3 Years
Target Costs (PMA)	$ 1.3MM	$ 3.1MM	$ 9.75MM	$ 3.6MM	$ 8.5MM	$ 41.3MM	$ 28.4MM	$ 36MM
Total (PMA):		$ 4.4MM	$ 14.2MM	$ 17.8MM	$ 26.3MM	$ 67.5MM	$ 100MM	$ 136MM

- The cost to deliver new technologies to patients via the FDA **PMA path** historically has been at least **2 - 5x more than 510k** products (especially for more novel products)

[Data above from 28 MedTech companies in the NEA portfolio]

Adoption Is Typically Slow & Costly

- Most physicians cautiously adopt new technologies
- Academia often plays an evaluation role with new technologies, but rarely drive adoption
- Most MedTech products have penetrated <15% of total potential market after 5 years on market

  [Source: Survey of Leading Med Tech Executives, Industry Analysts & Venture Capitalists]
- Most MedTech companies do not become profitable until they approach $75 - $100MM in sales

Conclusions

- Ecosystem is **fragile and sensitive** to changes in the **risk and cost** of innovation as the risk and cost are already substantial
- Innovation **driven by physicians and companies** collaborating
- **Patents are crucial** for obtaining and protecting investments

USIJ

Alliance of U.S. Startups and Inventors for Jobs

About USIJ: The Alliance of U.S. Startups and Inventors for Jobs (USIJ) was organized to provide information from inventors, universities, research institutions, start-ups and small companies regarding the importance of the patent system in facilitating investment in revolutionary new breakthroughs and to create a patent system which protects the inventions of those who create jobs, invent the technologies and products that create our future GDP and job growth and improve the human condition. USIJ members – which represent more than 40 life sciences and high-technology companies – come from a long line of inventors, start-ups, and research institutions who are inventing the technologies that will create our future economic growth. They are behind innovations that touch people's lives daily – from the LED displays we all use in our smart phones and TVs, to innovations that restore vision, hearing, and reduce the risk of surgery; impacting the lives of Americans each and every day. It can be found on the web at: www.usij.org

Structure

- Virginia Non-Stock Corporation
- Board of Directors
- Advisory Committee
- 501(c)(4) Status with the IRS (in Progress)

Guiding Principals

- Respect for Inventor's Property Rights
- Advocacy for Policies and Legislation that would lead to Improvement of Patent Quality
- Opposing Legislation that would lead to Post Patent Grant Review Process Abuse
- Advocacy of Policies and Legislation that Promotes Accessible and Effective Patent Enforcement
- Ensuring Compensation for Unauthorized Use of Patented Technology
- Deter Infringement of Valid Patent Claims
- Ensure that Investors are Compensated for Their Contributions to the Useful Arts

Objectives/Goals

- Recruit membership of inventors, innovators, universities, research institutions, start-ups and small companies, particularly in the High Tech and Life Science sectors.
- Educate on the importance of a strong patent system to facilitate investment in break-through technology and start-ups
- Develop and advocate for legislation which protects the intellectual property of inventors, innovators, universities, research institutions, start-ups and small companies
- Work with other entities and organizations with similar interests to magnify our voice
- Bring inventor's, CEOs and VCs to congress to explain how specific legislation will help/hurt the innovation ecosystem
- Create letters and other materials to make it easier for others to contact and influence their elected representatives.

Contact Information: If you would like to join or provide assistance, please contact us.

Name	e-mail	Position
Mike Remington	Michael.Remington@dbr.com	Executive Director
Charles Giancarlo	charliegian@yahoo.com	Chair
Angela Macfarlane	kam@forsightlabs.com	Vice Chair
Eb Bright	ebright@exploramed.com	Board Member
Roger Sippl	roger@sipmac.com	Board Member
Bernard Shay	bshay@miramarlabs.com	Board Member

Wisconsin Alumni Research Foundation

Carl Gulbrandsen,
Managing Director
March 21, 2014

WARF's Unique Organizational Structure

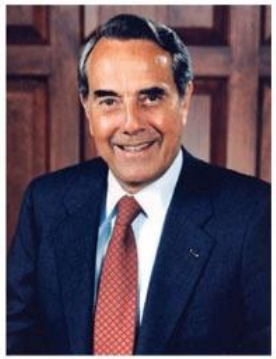
WARF: the UW–Madison's patenting and licensing arm

- Founded in 1925
- WARF is a separate, tax-exempt 501(c)(3) supporting organization
- Patent management organization for purposes of Bayh-Dole
- Earns revenues through licensing and investment of endowment built from licensing revenue
- Returns approx. $80 million/year to support research
- Governed by an independent board of successful alumni

Overview of Bayh-Dole

- Passed in 1980
- Uses the patent system to promote the utilization of federally sponsored inventions
- Encourages collaboration
- Favors small business
- Maintains local control

Birch Bayh



Bob Dole

Typical Technology Transfer Process

Identify new technology

- Conception
- Invention disclosure

Protect new technology

- Patent
- Copyright
- Trademark
- (Trade secret)

Development and commercialization strategy

- Proof of principle, prototyping, scale-up
- Marketing and Licensing
- Creating a new startup

Grace Period

- In the U.S.
  - Allows an applicant for patent to file and obtain a patent even though the invention was disclosed, provided the disclosure was made less than a year prior to the application for patent.

Importance of a Robust Grace Period to Universities

- Universities are open environments
  - Faculty publish discoveries
  - Faculty consult, give talks, go to meetings, etc.
  - Industry sponsors research and collaborates with faculty
  - Often faculty publish before they disclose to their university's technology transfer office
  - A robust grace period allowed one to file a patent application within a year of publication and obtain patent rights for the U.S.
  - Also allowed antedating other disclosures within the grace period. Show applicant invented before disclosure.

Grace Period

- Under the prior patent law (1952 Act; first to invent)
  - An applicant shall be entitled to a patent unless…:
    - The claimed invention was known or used by others in this country or patented or described in a printed publication anywhere before the invention by the applicant.
    - The invention was patented or described in a printed publication anywhere in the world or in public use or sale in this country more than a year before the application for patent.
- Under the AIA (first to file)
  - An applicant shall be entitled to a patent unless…:
    - The claimed invention was patented, described in a printed publication, or in public use, on sale or otherwise available to the public…
    - Exceptions for disclosures made one year or less before the effective filing date
      - The inventor(s) or another who obtained the subject matter directly or indirectly from the inventor(s) discloses
      - The subject matter disclosed had before such disclosure been disclosed

USPTO Construes the Grace Period Under AIA Narrowly

OBVIOUS ≠ SAME SUBJECT MATTER

Even if an intervening disclosure by a third party is obvious over an inventor-originated prior public disclosure, this is not a disclosure of the same subject matter and the 102(b)(1)(B) exception does not apply

Weak Grace Period

- Weak grace period more easily allows inventions to be stolen
- Weak grace period more easily allows inventions to be defeated
  - Disclosure by another of an obvious variation can defeat the invention

Impacts of Grace Period Confusion in Academia

- Actions and prior art that bar patentability will include public use, sales, publications, and other disclosures available to the public anywhere in the world as of the filing date, other than publications by the inventor within one year of filing
- Intervening publications based on the inventor's publication or presentations may be an issue
- Collaborations become more difficult and risky
- Confusion regarding prior art and urgency to file prior to disclosures to peers

Proposed "Innovation Act"

- HR 3309
- Numerous senate bills
  - Topics include:
    - Enhanced pleading requirements
    - Loser pays
      - » Contingent liability
    - Discovery limits
    - Demand letter prohibitions
    - Etc.

States Enacting "Patent Troll" Legislation

Eric Goldman
Contributor

FOLLOW

I write about Internet law, intellectual property and advertising law
full bio →

TECH 5/22/2013 @ 2:22PM | 8,181 views

Vermont Enacts The Nation's First Anti-Patent Trolling Law

4 comments, 2 called-out + Comment Now + Follow Comments

Efforts to crack down on patent trolling are escalating. Just a couple of years ago, Congress passed a major amendment of the Patent Act (the America Invents Act) with the hope that it would curb some abusive patent assertions. So aren't satisfied with the results of that an different bills (the SHIELD Act, the Pate Act and the End Anonymous Patents Act that would further restrict patent trolling

Forbes.com 5/22/13

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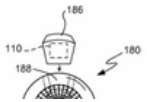
Mar 12, 2014, 1:05pm CDT | **UPDATED:** Mar 12, 2014, 2:31pm CDT

Wisconsin bill criminalizing patent troll letters passes Senate

Denise Lockwood
Reporter-
Milwaukee Business Journal



Milwaukee Business Journal 3/12/14

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Inter Partes Review and Post-Grant Review

New Regimes and New Strategies

From Lab to Market: How IP Secures the Benefits of R&D

CPIP at George Mason University School of Law and the Wisconsin Alumni Research Foundation

March 21, 2014

Arlington, VA

Robert Greene Sterne
Michelle K. Holoubek
Sterne, Kessler, Goldstein & Fox, PLLC

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Post-Issuance Patent Challenges

EPX: Ex Parte Reexamination

IPX: Inter Partes Reexamination

IPR: Inter Partes Review

PGR: Post Grant Review

CBM: Covered Business Method Patent Review

Why have contested cases at the PTO?

Rule 42.1(b): The rules should "be construed to secure the just, speedy, and inexpensive resolution of every proceeding"

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Filing Statistics*

Since September 16, 2012, there have been **927 petitions for *Inter Partes* Review** filed before the PTAB, and **124 petitions for Covered Business Method** patent review filed.

Tech Center	Name (If Available)	# of Filings
3600	Transportation, Construction, Electronic Commerce, Agriculture, National Security and License & Review	167
2800	Semiconductors, Electrical and Optical Systems and Components	165
2100	Computer Architecture, Software, and Information Security	161
2600	Communications	130
3700	Mechanical Engineering, Manufacturing, Products	130
2700, 2200, 2300	Other Electrical Arts	76
2400	Computer Networks, Multiplex communication, Video Distribution, and Security	68
1600	Biotechnology and Organic Chemistry	65
1700	Chemical and Materials Engineering	62
1300, 1500, 1100, 1200	Other Chemical and Biotechnology Arts	10
2900	Designs	5
3100, 3400, 3500	Other Mechanical Arts	3
		1042

Tech Center Summary:

- **Electrical: 767**
- **Bio/Chem: 137**
- **Mechanical: 133**
- **Designs: 5**

***as of March 7, 2014**

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Institution Statistics

IPR: To date, trial has been **instituted in 382 IPR proceedings** and **denied in 74 – 84%**

PGR: One filed in error – institution denied

CBM: Trial has been **instituted in 40 CBM proceedings** and **denied in 6** thus far – **87%**

Parties reached a settlement prior to a decision on institution in 52 IPRs and 10 CBMs.

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Trial Outcomes

AIA TRIALS INSTITUTED/DISPOSALS

		Trials Instituted	Joinders	Denials	Total No. of Decisions on Institution	Disposals			
						Settled	FWD*	RAJ**	Other***
IPR	FY13	167	10+	26	203	38	-	2	1
	FY14	172	1+	46	219	55	12	15	-
CBM	FY13	14	-	3	17	3	1	-	-
	FY14	20	-	3	23	8	8	-	-

+11 cases joined to 9 base trials for a total of 20 cases involved in joinder.
*Final Written Decisions on the merits.
**Judgments based on Request for Adverse Judgment.
***Includes terminations due to dismissal.

Source: USPTO as of 2/27/2014

The Board has issued **Final Written Decisions after the completion of the trial process in 19 proceedings** – 11 IPRs and 8 CBMs. In all but three of these proceedings, the Board has cancelled all claims for which trial was instituted. The Board has **cancelled 95.2% of all claims for which trial was instituted, and cancelled 82.9% of all claims that were initially challenged by the petitioner**.

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Inter Partes Review

- **When:** Later of 9 months after issue or termination of post-grant review.
- **What:** Patentability under §§ 102 & 103.
- **Standard for Proceeding:** "reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."
- **Estoppel:**
  - Petitioner "may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that inter-partes review."
  - Petitioner may not assert invalidity in a civil action "on any ground that the petitioner raised or reasonably could have raised during that inter partes review."

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Inter Partes Review

- **Procedure:**
  - **Patent Owner:**
    - Right to file a preliminary response.
    - Patent owner gets one opportunity to amend claims. Amendments are limited to cancelling a challenged claim or proposing a reasonable number of substitute claims.
  - **Petitioner:**
    - Cannot file if previously filed a civil action challenging validity
      - *Excludes counter claims for infringement actions*.
    - One opportunity to file written comments.
- **Limited Discovery:** Either party may conduct discovery "limited to—(A) the deposition of witnesses submitting affidavits or declarations; and (B) what is otherwise necessary in the interest of justice"
- **Appeal:** Either party may only appeal to the Federal Circuit.

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Post-Grant Review

- **When:** Up to 9 months after the date of issue or reissue.
- **What:** Any grounds for patentability under § 282 including §§ 101, 102, 103, and 112 (except Best Mode).
- **Standard for Proceeding:** "more likely than not that at least 1 of the claims challenged in the petition is unpatentable."
- **Estoppel:**
  - Same as IPR

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Covered Business Method Review

- **When:**
  - For patents filed before March 16, 2013: any time
  - For patents filed on or after March 16, 2013: any time PGR isn't available.
- **Estoppel:**
  - Petitioner "may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that post-grant review."
  - Petitioner may not assert invalidity in a civil action "on any ground that the petitioner raised during that transitional proceeding."
- **Standing**
  - Petitioner must have been sued or charged with infringement
    - Same as DJ

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Covered Business Method Review

- **Procedure:**
  - Special standing requirements
    - Petitioner must have been sued or charged with infringement
  - Special eligibility requirements
    - Patent must be related to a financial process or service
    - Not eligible if patent claims a “technological invention”
- **Special art provisions:** only 102(a) or 102(b) art is available to use – not 102(e); on-sale bar/prior use provisions not tested

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Patent Challenge Procedures

	Ex Parte Reexam	Inter Partes Reexam	Inter Partes Review	Post-Grant Review	Covered Business Method Review
When filed?	After grant	After grant until Sept. 15, 2012, then replaced by IP Review	After 9 months from grant	No more than 9 months after grant – only for patents filed on or after 3/16/13	Anytime for patents with pre-3/16/13 filing date For others, not when PGR is available
Showing	SNQ	"reasonable likelihood that the petitioner would prevail"	Reasonable likelihood of success	"more likely than not that at least 1 of the claims challenged in the petition is unpatentable" or important novel/ unsettled legal question	"more likely than not that at least 1 of the claims challenged in the petition is unpatentable" or important novel/ unsettled legal question
Estoppel	None	Issues raised or could have been raised	Issues raised or reasonably could have been raised by the petitioner	Issues raised or reasonably could have been raised by the petitioner	Issues raised or reasonably could have been raised by the petitioner
Discovery	No	No	Yes	Yes	Yes
Appeal	Only patentee can appeal to Board and CAFC	Both parties can appeal to Board and CAFC	Both parties can appeal to CAFC	Both parties can appeal to CAFC	Both parties can appeal to CAFC

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"Just, Speedy, and Inexpensive" Alternative to District Court Litigation?

Sterne Kessler Goldstein Fox
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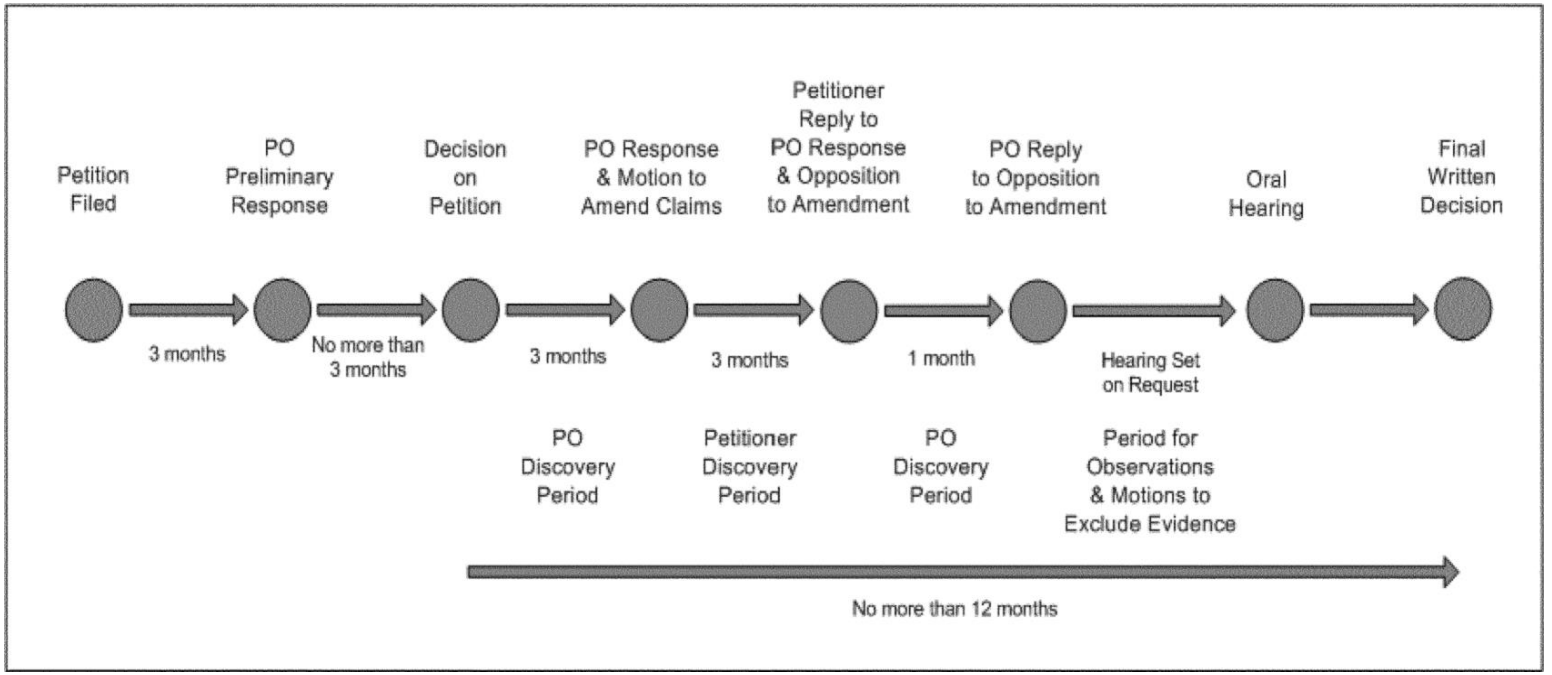
Speedy? Yes!

~18 months (max. 12 months from institution → final written decision, absent good cause or joinder).



Source: AIA Implementation, Official Patent Trial Patent Guide

http://www.gpo.gov/fdsys/pkg/FR-2012-08-14/pdf/2012-17908.pdf

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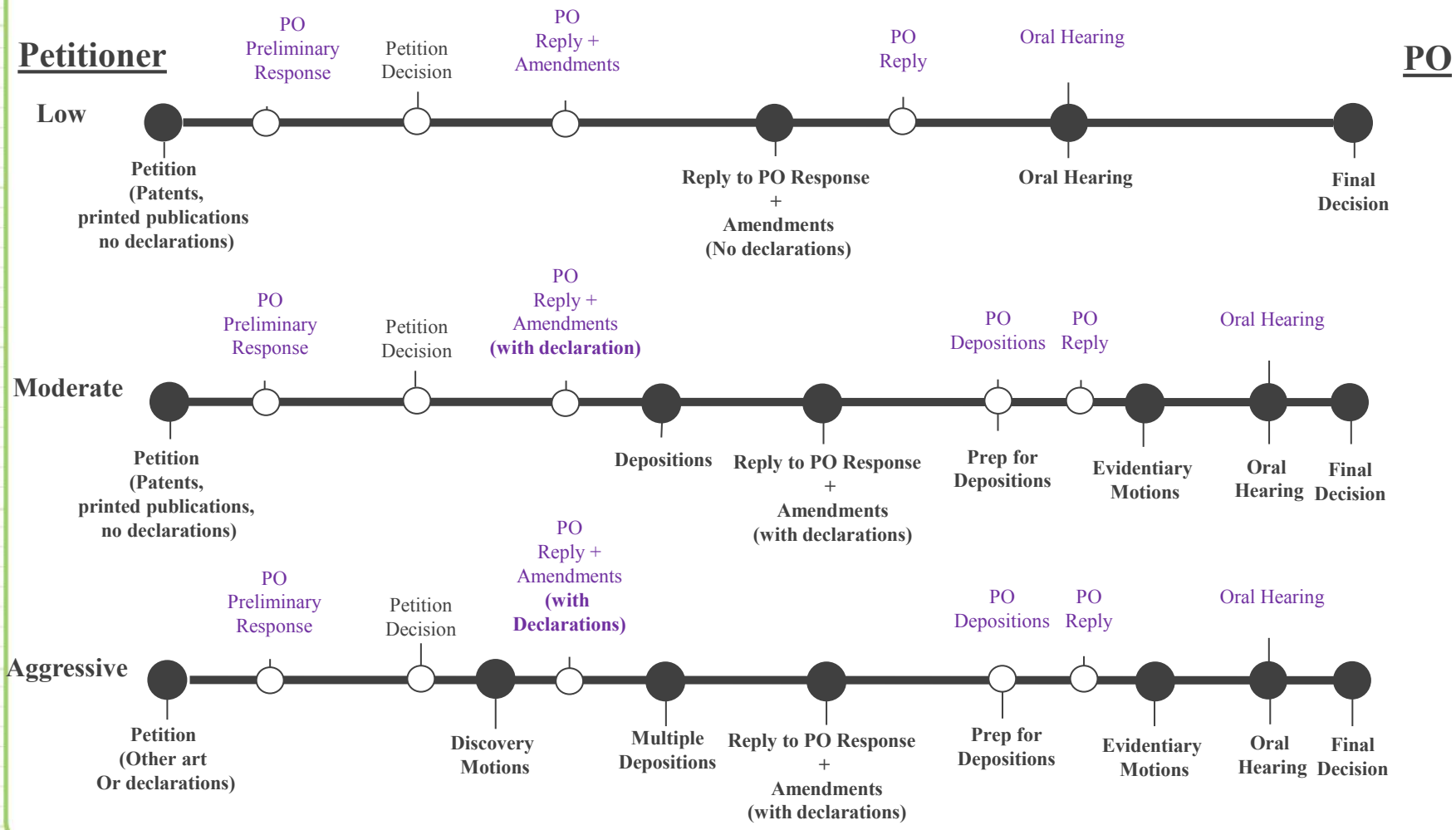
Inexpensive? Maybe!



Source: Michael V. Messinger, Director, SKGF

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Just? Depends on your position

- Petitioners likely prefer PTO, while Patent Owners likely prefer District Court
- Knowledge of the rules is essential!
- Comparisons with District Court practice guide strategies for managing concurrent proceedings

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Pro Hac Vice

- The Rule: 37 CFR § 42.10
- Time for Filing
- Content of Motion
  - statement of facts showing good cause
  - affidavit of good standing and statement that applicant is familiar with USPTO conduct rules and subject matter of IPR,
  - list of other pro hac admissions before the PTO.

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Claim construction

- Broader at PTAB: Broadest reasonable construction in light of the specification, versus ordinary and customary meaning in D.Ct./Fed. Circuit
- Difference results from patent owner being able to amend claims in an IPR but not in court, no presumption of validity at PTAB
- What this means for patent owners

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Ability to Amend

- Amendments:
  - Patent owner may file one motion to amend the patent by:
    - cancelling any challenged patent claim; or
    - for each challenged claim, proposing a reasonable number of substitute claims.
  - Additional motions permitted upon:
    - joint request of patent owner and petitioner to advance settlement; or
    - request of the patent owner for good cause.
  - Amendment cannot enlarge claim scope

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Ability to Amend

- Patent Owner must:
  - Show the proposed substitute claim is patentable over the prior art of record, AND
  - over prior art not of record but known to the patent owner
- Not entered as of right

Discovery and Depo of Experts

- Routine discovery
- Additional discovery
  - Standard
    - Limited to “necessary in the interests of justice” in IPR
    - Showing of good cause needed in PGR
  - 5 factor test from *Garmin International v. Cuozzo Speed Tech*
    - More than a possibility and mere allegation
    - Litigation position and underlying basis not allowed
    - Ability to Generate Equivalent Information by Other Means
    - Easily Understandable Instructions
    - Requests Not Overly Burdensome to Answer
- Evidentiary objections subject to tight deadlines

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Discovery – Motion to Seal

- Confidential material must be accompanied by a Motion to Seal
- BUT at PTO, "the file of any proceeding … shall be made available to the public." Sec. 316(a)(1)
- Must show good cause to keep a document sealed.
  - The Board will weigh the public interest in open proceedings versus the need to keep a document secret
- If motion is not granted, may expunge information
- Papers will be made public 45 days after termination of trial unless there is a motion to expunge.

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Discovery – Protective Orders

- Board has default PO in Trial Practice Guide – It is best to use it.
  - Any deviation must be explained and accepted
  - Negotiate PO and present as joint submission
- A PO from another proceeding will not suffice

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Settlement

- Consider having a separate agreement just for PTO litigation
  - Joint request of patent owner and petitioner will terminate proceeding
  - No estoppels
- Not necessarily accepted
- Must be submitted under seal

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Estoppels

- PGR and IPR come with significant estoppel provisions
  - Petitioner may not assert invalidity of claim in civil action or other PTO proceeding on any ground that Petitioner "**raised or reasonably could have raised**" during proceeding
- CBM not so restrictive
- Attach at final written decision of PTAB
- Results in race to the Federal Circuit

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Stays

- Granted more often than not in IPR
- CBM has statutory 4 factor test
- Immediate interlocutory appeal to Federal Circuit available

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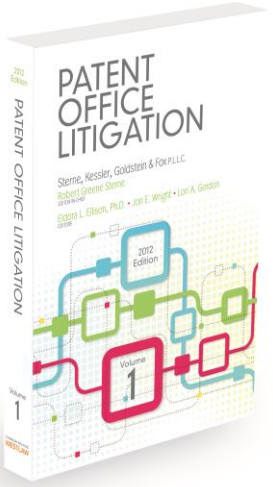
Resources



http://www.skgf.com/book

Lunch and Keynote Address by the Hon. Randall R. Rader, Chief Judge of the U.S. Court of Appeals for the Federal Circuit

#LabtoMarketIP

Panel 3 *The Shrinking Scope of Patentable Subject Matter*

- Prof. Chris Holman, University of Missouri-Kansas City School of Law
- Prof. Kristen Osenga, University of Richmond School of Law
- Hans Sauer, *Deputy General Counsel for IP*, Biotechnology Industry Organization
- Katharine Wolanyk, *President*, Soverain Software
- *Moderator:* Prof. Adam Mossoff, George Mason University School of Law

#LabtoMarketIP

The Under-Appreciated Role of Patents in the Development and Commercialization of Molecular Diagnostic Tests

Chris Holman
UMKC School of Law

George Mason University School of Law
March 21, 2014

Myriad Genetics – US Patent No. 7,993,835 (Aug. 9, 2011)

- 1. A method for detecting a mutation in a BRCA2 allele comprising: **analyzing a BRCA2 nucleic acid from a sample obtained from a human subject**; and detecting a mutation in said nucleic acid wherein said mutation results in the deletion of five nucleotides beginning at position 4,633 of a BRCA2 cDNA.

Myriad Genetics – US Patent No. 7,993,835 (Aug. 9, 2011)

- 3. A method of genotyping, comprising: **obtaining a tissue sample or cells from a human patient identified** as, or suspected of, having an increased predisposition to breast and ovarian cancer; and detecting in said tissue sample or cells a deletion of five nucleotides in a BRCA2 allele beginning at the cDNA position of 4,633.

Genomic Health, Inc. – US Patent No. 8,273,534 (Sept. 25, 2012)

- 1. A method for predicting a likelihood that a human patient with an epidermal growth factor receptor (EGFR)--expressing colorectal cancer will exhibit a beneficial response to an EGFR inhibitor comprising: (a) **measuring, in a tumor sample obtained from the patient**, a level of an RNA transcript, or its expression product, for each of solute carrier family 26, member 3 (SLC26A3), amphiregulin (AREG), epiregulin (EREG) and dual specificity phosphatase 6 (DUSP6), (b) normalizing the level of the RNA transcript, or its expression product, for each of SLC26A3, AREG, EREG, and DUSP6 to obtain a normalized expression level for each of SLC26A3, AREG, EREG, and DUSP6; and (c) using the normalized expression level to determine the likelihood that the patient will exhibit a beneficial response to an EGFR inhibitor, wherein the normalized expression levels of SLC26A3, AREG, and EREG are positively correlated with the likelihood that the patient will exhibit a beneficial response to the EGFR inhibitor, and wherein the normalized expression level of DUSP6 is negatively correlated with the likelihood that the patient will exhibit a beneficial response to the EGFR inhibitor.

Genomic Health, Inc. – US Patent No. 8,273,537 (Sept. 25, 2012)

- 1. A method of predicting clinical outcome for a human subject diagnosed with colorectal cancer following surgical resection of said cancer, comprising: **determining normalized expression levels of RNA transcripts of CMYC and Ki-67, or expression products thereof, in a biological sample comprising cancer cells obtained from said human subject**, and; predicting the likelihood of a positive clinical outcome for said human subject based on said normalized expression levels of RNA transcripts of CMYC and Ki-67, or expression products thereof, wherein said normalized expression levels of RNA transcripts of CMYC and Ki-67, or expression products thereof, are positively correlated with an increased likelihood of a positive clinical outcome.

Critics of "Gene Patents" Focus on Societal Cost of the Right to Exclude

- Potential impediment to research
  - But look at the number of US research publications on BRCA genes in spite of Myriad patents
- Availability to patients
  - But look at number of US patients that have obtained BRCA test
- Confirmatory or "second opinion" testing
  - Largely an illusory problem?

Critics Acknowledge Positive Role of Patents in Drug Development

- Patents clearly limit the number of companies providing a drug (often only the innovator company) and cause higher prices
- Most critics of gene patents acknowledge that patent protection for drugs is justified
- Implicit is the assumption that patents are not necessary to commercialize diagnostic tests

Invention of Diagnostic Tests Requires Substantial Investment

- "Myriad invested millions of dollars, including money obtained via public grants, in an effort to locate and sequence those genes in the early-to-mid-1990s."
  - IN RE: BRCA1- AND BRCA2- BASED HEREDITARY CANCER TEST PATENT LITIGATION

Invention of Diagnostic Tests Requires Substantial Investment

- Companies like Myriad and Genomic Health invest millions to develop diagnostic tests
- Isolation of gene is only the first step, identification of clinically significant correlations requires large data sets and analysis
  - Lack of patent protection discourages sharing of data

Validation and Reimbursement

- A patent holder is incentivized to invest in the research to validate diagnostic test and obtain reimbursement for patients
- "Myriad has secured and maintained in-network contracts with more than 530 private payors to ensure that more patients have insurance coverage for testing, and the lowest possible out-of-pocket expense."
  - IN RE: BRCA1- AND BRCA2 []PATENT LITIGATION

Patient and Physician Awareness

- A patent holder like Myriad's incentivized invest in educating patients and physicians as to the availability of genetic test

The Role of Regulation

- One major difference between drugs and diagnostic tests is the level of regulatory oversight
  - Narrow patent claim is sufficient to block generic drug competition, but generally not sufficient to preclude diagnostic competition
  - If FDA increases regulation of diagnostic tests, patents could become more important in incentivizing investment in clinical studies to support regulatory approval

Software Patent Schemas

Kristen Osenga
University of Richmond School of Law

Overview

- Patent eligible subject matter
- Software patent mess
- Software patent schemas
- Debugging the schemas

Patent eligibility - briefly

- § 101 (process, machine, manufacture, composition of matter)
- Exceptions
  - Abstract ideas, laws of nature, natural phenomena
- SOFTWARE

Software patent mess

- SCT Trilogy
  - *Benson*, *Flook*, and *Diehr*
- Useful, concrete, & tangible result
  - *State Street Bank, AT&T*
- Machine or transformation
  - *Bilski*
- Who knows…
  - *CLS Bank*

Software patent schemas

- What a schema is?
- Software's schemas
  - Bad patent schema
  - Patent troll schema
- Schemas driving precedent
- Schemas driving current cases, legislation

Debugging the schemas

- Be aware of schemas infiltrating decision making
- Focus on the question at issue
  - What is “abstract”?

- For complete discussion of “Debugging Software’s Schemas,” *see* George Washington University Law Review, *forthcoming* 2014.

Association for Molecular Pathology v. Myriad Genetics, Inc. (569 U.S. __ (2013))

Observations on the shrinking scope of patentable subject matter

Hans Sauer
Deputy General Counsel
Biotechnology Industry organization

The claims:

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.

- Common type of generic claim – defined by the encoded amino acid sequence (1,863 AA for BRCA1)
- Captures cDNA and genomic sequence.
- For natural genes – often no single definitive nucleotide sequence (polymorphisms). Use of “coding for” language allows for more unambiguous – but also generic - claiming.
- “Coding for” language prevents design-around by making synonymous substitutions.
- Doesn’t capture deleterious mutations (encodes only WT protein).

The claims (2):

5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.

(i.e. having at least 15 nucleotides of an 'isolated DNA coding for a BRCA1 polypeptide of SEQ ID NO:2.')

- Less common today – when used, explicit for "XX contiguous nucleotides of…"
- Intended to capture probes and primers.
- Dependent (?) claim – but much broader in scope. Captures all fragments, from 15 bp all the way to full-length (about 84 kb for BRCA1) or beyond.
- Claim construction question: Fragments of the BRCA gene? Fragments of any DNA that encodes a BRCA protein? Any DNA that shares 15 contiguous bp with the BRCA gene? Any DNA that shares 15 nucleotides with any DNA that encodes a BRCA protein?

The claims (3):

2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.

- SEQ ID No. 1 is the cDNA sequence. (5.5kb for BRCA1 and 10.2 kb for BRCA2)
- Limited to particular consensus sequence
- Narrow claim

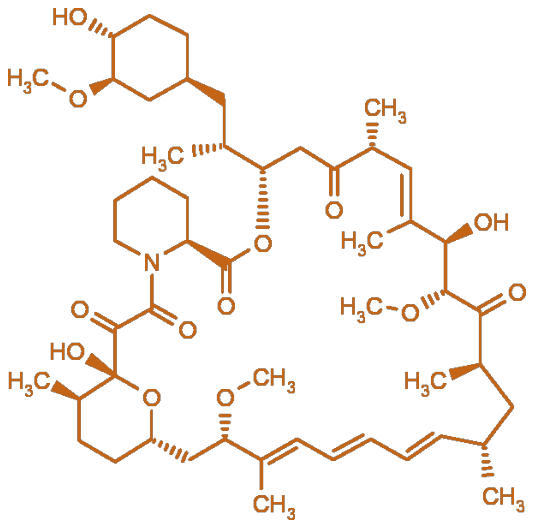
How many patents are affected?

- The question presented was “are human genes patentable?”
- All commentators agree that the decision, at a minimum, applies to all DNA and RNA having naturally-occurring sequences of human, animal, plant, or microbial origin.
- An estimated 8,700 unexpired U.S. patents contain at least 1 claim of this type.
  - 40% relate to use in human medicine
  - 60% relate to other fields, such as veterinary medicine, agriculture, food and beverage manufacturing, industrial enzymes or bioenergy
  - *Nature Biotechnology* 31(5) (2013) 404-410

The number of affected patents could be much larger if the opinion applies to claims on other “naturally occurring things.”

What if it's not a nucleic acid?

- Other molecules have been extracted, purified, or enriched from natural materials
- E.g. sirolimus (Rapamune®) is produced by *Streptomyces hygroscopicus* (a soil bacterium from Easter Island).
- If DNA isolated from *Streptomyces hygroscopicus* is not patent eligible, would a macrolide antibiotic isolated from the same organism be patent eligible?
- Why or why not? Your thoughts?



What if it's not a nucleic acid? (2)

- Claims to pure or enriched preparations of defined strains of bacteria or fungi or certain stem cell lines?

- For example, a number of EPA-regulated commercial crop protection products consist of selected strains of bacteria or combinations thereof. *Bacillus thuringiensis* and B. *subtilis* strains are used in organic insect control; *B. pumilus* is used as a biofungicide. Naturally-occurring fermentation products such spinosad and avermectin are commercially marketed for insect and mite control.

- *Consumer Watchdog v. WARF*, Case No. 13-1377 (Fed Cir.) (argued that patents on stem cell lines are patent-ineligible under *Myriad* decision).

Synthetic copies or fragments of natural molecules?

- A laboratory-made synthetic DNA molecule "may be indistinguishable" from a natural genomic DNA if both have the same nucleic acid sequence.
- Accord: a chemically synthesized medicinal molecule be "indistinguishable" from a botanical (natural) medicinal molecule if both have the same molecular structure?
- Synthetic compounds that are not extracted from natural source materials:
- E.g. Fab fragments, or therapeutically useful GLP-1 analogues for blood glucose control.
  - Exenatide (Byetta®) is a fragment of a peptide originally identified in the saliva of Gila Monsters. The active compound can be extracted from the natural venom, but is produced synthetically for pharmaceutical purposes. Byetta® was approved in 2005.
- Synthetically-produced versions of naturally-occurring medicinal molecules
  - E.g. pilocarpine is extracted from jaborandi plants, but can be produced through de novo synthesis. Taxol can be extracted from the bark of Pacific yew trees, but is today more efficiently (and sustainably) produced through a semi-synthetic process that starts with extracted precursors from yew needles.

The sufficiency of cDNA claims

- *"cDNA is the commercially most important form of DNA in biotechnology, and its confirmed patentability provides important assurances for much of the industry. Companies that use cDNA for recombinant protein expression will continue to have protection for their particular expression constructs."*
- But cDNA claims don't work for everyone:
  - Genes of bacteria, blue-green algae, mitochondria, chloroplasts, and many viruses cannot be represented in a cDNA that would be patentable under the Supreme Court's reasoning, because these genes do not contain introns that could be edited out.
  - A significant number of eukaryotic genes are "intronless" and cannot be reconfigured into patentable cDNA. E.g. 20% of all rice and arabidopsis genes are single-exon; 3-5% in teleost fishes; for humans, the reported range is 10-12%.
  - The majority of genetic material is intergenic and intronic.
- The universe of genetic material declared "off limits" may be much larger than commonly assumed.

Going forward:

- USPTO preliminary examiner memo, Jun. 13
  - Reject claims to naturally occurring nucleic acids or fragments thereof. Withdraws all allowed cases from issue.
- Market entry
  - Within days of decision, several commercial competitors announce launch of competing BRCA testing. Myriad stock price erodes over following weeks by 20-25%.
- Follow-on legislation announced
  - June 20, DNC Chairwoman Debbie Wasserman Schultz announces follow-on legislation based on the ruling.
- Expansion beyond nucleic acids
  - July 2nd PubPat Foundation files brief in Federal Circuit, arguing invalidity of claims on stem cell lines under *Myriad.*
- Follow-on litigation
  - Litigation of Myriad's other claims and patents against Ambry Genetics, Gene by Gene, Invitae, LabCorp, Quest.

Going forward: (2)

- Calls for NIH march-in and compulsory licensing
  - July 12, Senate Judiciary Committee Chairman Pat Leahy sends open letter to NIH Director Collins, urging exercise of federal march-in authority under Bayh-Dole.
- CAFC, Feb. 5 oral arguments in *In Re Roslin Institute:*
  - A cloned sheep is a product of nature – "Myriad is very clear on this point." (J. Moore)
- March 4 - USPTO issues examination guidelines, expands *Myriad* to
  - *"chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (e.g., fruits, grains, meats and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (e.g., rocks, sands, soils); nucleic acids; organisms (e.g., bacteria, plants and multicellular animals); proteins and peptides; and other substances found in or derived from nature."* This will be done regardless of whether limitations such as "isolated," "recombinant," or "synthetic" are part of the claim.

THE SHRINKING SCOPE OF PATENTABLE SUBJECT MATTER

Katharine Wolanyk
President, Soverain Software
March 21, 2014

Alice Corporation Pty. Ltd. v. CLS Bank International

- Oral argument March 31, 2014
- Considerable case interest
  - 11 amicus briefs at the cert petition stage
  - 41 amicus briefs at merits stage
  - U.S. Solicitor General brief, argument
- Decision expected by end of Term

Alice Question Presented

Whether claims to computer-implemented inventions – including claims to systems and machines, processes, and items of manufacture – are directed to patent-eligible subject matter within the meaning of 35 U.S.C. § 101 as interpreted by this Court.

Patent-Eligible Subject Matter

35 U.S.C. § 101:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

Judicially-Created Exceptions

The Supreme Court has identified three exceptions to § 101's broad patent-eligibility principles:

- laws of nature
- physical phenomena
- abstract ideas

What is an “abstract idea?”

- “The problem is that no one understands what makes an idea ‘abstract,’ and hence ineligible for patent protection.”

  Mark Lemley, et al., *Life After Bilski*

- “As the Federal Circuit’s deeply-divided en banc opinion … abundantly demonstrates, the abstract idea exception has proven extremely difficult to apply to computer-implemented inventions.”

  IBM amicus brief

CLS Bank International v. Alice Corporation Pty. Ltd.

- Trial court invalidated all claims on § 101
- CAFC panel reversed
- CAFC *en banc* issued seven decisions:
  - One-paragraph per curiam majority opinion
  - Plurality opinion as to method claims
  - 5-5 split as to system claims
  - Net result: all claims invalid but no precedential rationale

What's At Stake

"And let's be clear: if all of these claims, including the system claims, are not patent-eligible, this case is the death of hundreds of thousands of patents, including all business method, financial system, and software patents as well as many computer implemented and telecommunications patents."

Judge Kimberly Moore, in her dissenting-in-part opinion

A Brief History of Software Patents (And Why They're Valid)

Adam Mossoff

SEPTEMBER 2013

CENTER FOR THE PROTECTION OF INTELLECTUAL PROPERTY

A Brief History of Software Patents (and Why They're Valid)

ADAM MOSSOFF

Today, there is significant public debate over patents on the digital processes and machines that comprise computer software programs. These are often referred to as "software patents,"[1] but this is an odd moniker. Aside from the similarly mislabeled debate over "DNA patents,"[2] nowhere else in the patent system do we refer to patents on machines or processes[3] in a specific technological field in this way; for instance, people do not talk about "automobile brake patents" or "sex toy patents" as their own category of patents deserving of approval or scorn. (Yes, there are sex toy patents, and there are infringement lawsuits in which none other than Judge Richard Posner, a strident critic of today's patent system,[4] ruled that a particular sex toy was obvious and therefore unpatentable.[5])

Unfortunately, the policy debates today about "software patents" are rife with extensive confusion and misinformation about what these patents are and even about what "software" is. Even the Court of Appeals for the Federal Circuit is deeply confused about these patents, as evidenced by its highly fractured en banc decision in *CLS Bank v. Alice Corp*.[6] In 135 pages of numerous concurring and dissenting opinions that accompany the one-paragraph per curiam majority opinion, the *CLS Bank* court threw patent doctrine in this booming, innovative industry into even more disarray.[7] Judge Lourie's concurring opinion, joined by a substantial number of his colleagues, essentially argues that computer programs are unpatentable.[8] In her dissenting-in-part opinion, Judge Kimberly Moore rightly observed that Judge Laurie's opinion (and the fractured *CLS Bank* decision itself) represents "the death of hundreds of thousands of patents, including all business method, financial system, and software patents as well as many computer implemented and telecommunications patents."[9] Commentators have been equally critical of *CLS Bank*.[10]

Given the widespread confusing rhetoric and the concomitant doctrinal upheaval, a little historical perspective can be helpful and illuminating. First, knowing the historical evolution of software patents—even in classic "potted history" form[11]—is important because it reveals that the complaints today about intellectual property (IP) protection for computer programs are nothing new. Opposition to IP protection for computer programs has long existed—predating the Federal Circuit's 1998 ruling that business methods are patentable,[12] predating the Federal Circuit's 1994 ruling that computer programs are patentable as the equivalent of a digital "machine,"[13] and predating the Supreme Court's 1980 decision that a computer program running a rubber vulcanization process was patentable.[14] In fact, computer programmers and others initially opposed extending copyright protection to computer software programs, as I will discuss shortly.

Second, this history reveals that the shift in legal protection from copyright law in the 1980s to patent law in the 1990s was not a result of strategic behavior or rent-seeking by commercial firms who exploited their access to the halls of power in Congress (or somehow duped the courts into providing them the same legal protections). To the contrary, this historical evolution from copyright to patent law represented a natural legal progression as the technology evolved from the 1960s up to the mid-1990s. As it happens in our common law system — precisely because it is designed to happen this way — legal doctrines evolve in response to changes in innovative technological products and commercial mechanisms that, through the marketplace, spread these new technological values throughout the world.

It bears emphasizing that this is a "potted history" (in a non-pejorative sense). In a short essay I cannot recount every historical detail, and space constraints will require me to compress some developments into a simplified version. Of course, one should consult more detailed historical accounts of the digital revolution and its follow-on revolutions. For example, I recommend T.R. Reid's *The Chip* (2001), which provides an engaging and accessible recounting of the scientific and technological developments that made the Digital Revolution possible.

What is a "Software Patent"?

Before we can address the history, though, it is necessary to get clear on what exactly we mean by a "software patent." One of the primary problems with the term "software patent" is that, like other widely used terms in the patent policy debates today,[15] it lacks an objective definition. For instance, many critics of "software patents" attack them as patents on "mathematics"[16] or patents on a "mathematical algorithm,"[17] but this is sophistry. As commentators have repeatedly recognized, a word processing program like Word for Windows or a spreadsheet program like Excel are not the same thing as 2+2=4,[18] and the fact that computer programs use mathematics is an argument that proves too much. All patented innovation uses mathematics; in fact, physicists love to say that the universal language of the universe is mathematics.[19] So if taken seriously, the argument that a "web browser, spreadsheet, or video game *is* just math and therefore it's not … eligible for patent protection,"[20] would invalidate all patents if applied equally to other inventions, especially processes and methods. All inventions of practically applied processes and machines are reducible to mathematical abstractions and algorithms (e.g., a patentable method for operating a combustion engine is really just an application of the law of PV=nRT, the principles of thermodynamics, and other laws of nature comprising the principles of engineering).

Complicating things even further, the term "software patent," even when it is not being used in a way that invalidates all patents, is often used to refer to many different types of patented innovation. The term has been used to encompass such inventions as electrical patents and business method patents simply because the patented innovation uses some type of computer software program in its implementation. (As discussed in Hal Wegner's famous patent law listserv shortly after the GAO Report was released, one concern with the GAO Report is its surprising, and what many think is unrealistic, claim that

As commentators have repeatedly recognized, a word processing program like Word for Windows or a spreadsheet program like Excel are not the same thing as 2+2=4, and the fact that computer programs use mathematics is an argument that proves too much.

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"By 2011, patents related to software made up more than half of all issued patents."[21] This only makes sense if one includes not just classic computer programs among total issued patents, but any and all inventions that require some type of computer program in their implementation.[22])

For ease of reference given the ubiquity of this term in the policy debates, I will refer to "software patents" in this essay, but I will limit this term solely to patents on a set of machine-readable instructions that direct a central processing unit (CPU) to perform specific operations in a computer.[23] In short, "software" means a *computer program*, such as a word processing program (e.g., Word), a spreadsheet (e.g., Excel), or even programs run on computers on the Internet, such as Google's search algorithm, Facebook, eBay, etc. Of course, the reality is far more complicated than this, but that's not the point of this essay.

In fact, few people realize the vast numbers of valid and valuable patents on computer programs. The entire Internet rests on patented innovation in computer programs: the packet-switching technology used to transmit information over the Internet was patented by Donald Watts Davies (Patent No. 4,799,258). Robert Kahn and Vinton Cerf, the inventors of the TCP/IP packet-switching protocol, later patented their follow-on invention of a packet-switching version of a knowbot[24] (Patent No. 6,574,628). Larry Page and Sergy Brin patented their famous search algorithm when they were graduate students at Stanford, and such patented innovation was a reason why Page and Brin received venture-capital funding for their start-up company, Google (there are several patents, but Patent No. 6,285,999 is one of the core ones). There are slews of other valid patents on technologically and commercially valuable computer programs, such as an early one from

1993 for one of Excel's core spreadsheet functions (Patent No. 5,272,628).

To understand why these and many, many other patents on computer programs are both valuable and valid, it is necessary to understand whence computer programs came, how they changed in both their technological and commercial function after the 1970s, and why patent law was extended to secure this technological innovation in the early 1990s.

The Digital Revolution

Our story begins in the early years of the Digital Revolution with the invention of the integrated circuit in 1958-1959 (independently invented by Jack Kilby and Robert Noyce).[25] At that time, "software," at least as we now understand this term, did not mean what we think this term means today. Software was designed for specific computers and only for those computers. To wit, what worked on a specific IBM mainframe did not work on a DEC minicomputer (which was the size of a refrigerator).

(A young reader might ask, "Who is DEC?" Good question, young man or woman! The Digital Equipment Corporation (DEC) was one of the early leading firms manufacturing computers in the high-tech industry in the 1960s, ultimately bringing in multi-billion dollar revenues.[26] Its founder and CEO, Ken Olson, was admired by a young Bill Gates.[27] Olson also infamously said in 1977, "There is no reason for any individual to have a computer in his home."[28] That's why DEC is no longer around and why young people today no longer remember this company.)

The Copyright Controversy

Despite the start of the Digital Revolution a mere 60 years ago, its early growing pains have become the equivalent of "ancient history." For this reason, many people no longer remember that the protection of computer programs under copyright—something accepted today as an allegedly "obvious" legal alternative to patent protection—was originally disputed rigorously by programmers and others. The question of whether computer programs were copyrightable was a tremendous flashpoint of controversy for much of the 1960s and 1970s, which is ironic given that people today blithely assert that we don't need patent protection for computer programs because "copyright protection … makes patent protection mostly superfluous."[29] (This claim is also false, as the historical development makes clear and as will be explained shortly.)

Despite substantial controversy, in 1964 the Registrar of Copyrights started to register copyright protection for software code for computer programs.[30] Although there was no direct legal challenge to the Copyright Registrar's decision to begin registering copyrights for computer programs, the public policy debates did not go away.[31] The controversy continued, especially in the courts, for almost two decades,[32] and it was not resolved until Congress enacted the Computer Software Copyright Act of 1980,[33] which specifically authorized the protection of software code by the Registrar of Copyrights under the Copyright Act. In sum, opposition to IP protection for computer programs has existed from time immemorial, regardless of whether it was copyright or patent.

The PC Revolution

It is significant that the Computer Software Copyright Act was enacted in the early 1980s because it was during this time—the late 1970s and early 1980s—that the PC Revolution began ("PC," for the uninitiated, means Personal Computer). This is the point in time that marks the shift away from hardware and software as a unified, single product, to hardware and software as distinct products. This is the revolution brought to us by the young hackers and computer geeks of the 1970s—Steve Jobs, Steve Wozniak, Bill Gates, Nathan Myrhvold, etc.—who conceived, designed, and implemented the idea of an operating system (OS) running on a CPU that could serve as the operational platform for any computer program written by anyone performing any tasks, such as playing tic tac toe or blinking lights on a circuit board in a certain pattern (just some of the original programs end-users could write and operate in the 1970s) to the sophisticated word processing, spreadsheet, and computer-assisted design (CAD) programs that began to be sold and used on PCs in the 1980s.

The significance of the PC Revolution is that computer software programs now became* separate products *that consumers could purchase, install, and use on their PCs.

Any programmer can easily replicate the GUI or other features of a commercially successful computer program—copying the valuable function of the program—without copying the literal software code that created this valuable function.

The significance of the PC Revolution is that computer software programs now became *separate products* that consumers could purchase, install, and use on their PCs (either an "IBM Compatible" or a Mac). In fact, computer programs came in a *box* that consumers physically took off shelves and purchased at checkout registers at retail stores, such as at an Egghead Software outlet. (Egghead Software closed all its retail stores in 1998 due to the dominance of the Internet as a medium over which to order DVDs, and, eventually, through which end-users now directly purchase and download in 30 seconds their new software products or apps.[34])

The significance of a computer program becoming a separate product is that the *value* in software, what the consumer was seeking in purchasing it from the retailer, was the *function* of the program as experienced by the consumer (called an "end-user" in high-tech parlance). For instance, it was the value in the ease of use of a graphical user interface (GUI) of a particular word processing program, such as Word for Windows, that made it more appealing to consumers than the text-based commands of older word processing programs, such as WordPerfect. Or it was the pull-down menu in a Lotus1-2-3, the first widely successful spreadsheet program. The end-user now had a word processing program with many functions in it, such as editing text, italicizing text, "cutting" and "pasting," changing margins for block quotes, etc. *This* was the value in the product sold to the consumers, and thus *this function* is what designers of computer programs competed over for customers in the marketplace. For instance, few people today remember the battle in the late 1980s and early 1990s between WordPerfect (a text-based word processor developed for the text-based command system of DOS) and Word (a pull-down menu and button-based "point and click" GUI word processor for the Windows and Apple GUI OS).

This is not a radical or novel insight; it is a mundane fact recognized by many who have worked in the high-tech industry for the past several decades. Back in 2006, Nathan Myhrvold recounted how even many people working in the high-tech industry did not think that a company that solely made software like Microsoft could succeed. In 1987, he explained that he attended a

> *big industry conference in the PC industry. And there was a panel discussion I participated in—"Can Microsoft Make it Without Hardware?" I swear. Now, we had a proposition and the proposition was that not only can you make software valuable without hardware; software was actually a better business without hardware, because if you separated yourself off and you just became a software company you could focus on making the software best….An independent software company can target everybody's stuff.*[35]

What Myhrvold means by "target[ing] everybody's stuff" is that a company like Microsoft could succeed in selling computer programs that provided functional value to a vast array of end-users. Thus, for instance, Robert Sachs, a patent attorney who specializes in high-tech innovation and serves as an evaluator for high-tech standards, explains that the "vast majority of value in software comes not from some deeply embedded algorithm that can be protected by trade secret. Rather, it comes from the creation of new functionality that has immediate and apparent value to the end user, whether that's a consumer or an enterprise."[36]

In the late 1980s and early 1990s, this amazing development in new technology and new commercial intermediaries in delivering new computer programs to consumers created a problem: any programmer can easily replicate the GUI or other features of a commercially successful computer program—copying the valuable function of the program—without copying the literal software code that created this valuable function. In sum, the code becomes distinct from the end-user interface or the function of the program itself.

And there's the rub (to paraphrase the Bard): copyright protects someone only against copying of their literal words, not the broader idea or function represented by those words. In copyright law, this is the well-known legal rule referred to as the idea/expression dichotomy (express words are protected under copyright, but ideas are not).[37]

It is also reflected in the equally hoary legal rule that copyright does not protect utilitarian designs.[38]

This issue was brought to a head in the famous copyright case of *Lotus v. Borland*.[39] Lotus, the creator and owner of the very famous spreadsheet program Lotus 1-2-3, sued Borland in 1990 for copying Lotus's innovative pull-down menus in Borland's spreadsheet program, Quattro Pro. Lotus's design of the pull-down menus in Lotus 1-2-3 —these are now standard in all GUI-based computer programs—made it very efficient to use and this was a major reason for its commercial success.

The *Lotus* case was active for five years, and ultimately resulted in a trip to the U.S. Supreme Court, which split 4-4 in affirming the lower court (Justice Stevens recused himself), and thus the Supreme Court didn't hand down a precedential opinion.[40] As a result of the 4-4 split, the lower appellate court's decision (the Federal Court of Appeals for the First Circuit) was affirmed by default. The First Circuit held that Lotus could not copyright its pull-down menus because these were a functional "method of operation," i.e., a utilitarian design, and not an expressive text capable of receiving copyright protection.[41] The First Circuit and the four Justices who affirmed the First Circuit were correct in applying long-standing and fundamental copyright doctrine in denying copyright protection to the *functionality* of a computer program.

By the mid-1990s, as represented in the famous *Lotus v. Borland* case, it was clear that copyright could no longer adequately secure the value that was created and sold in software programs by the fast-growing high-tech industry. The *value* in a software program is the *functionality* of the program, such as Lotus 1-2-3, Excel, WordPerfect or Word for Windows. This function was the reason why consumers purchased a program, installed it and used it on their computers, whether an Apple computer or a Windows machine. But this functionality could be replicated using myriad varieties of code that did not copy the original code, and copyright did not protect the functional components of the program that this code created for the end-user—and for which the end-user purchased the program in the first place.

The Shift to Patent Law

This simple legal and commercial fact—copyright could not secure the real value represented in an innovative computer program—explains why in the mid-1990s there was a shift to the legal regime that could provide the proper legal protection for the innovative value in a computer program: patent law. As the Supreme Court has repeatedly recognized in contrasting patents against other IP regimes, such as copyright and trademark, "it is the province of patent law" to secure "new product designs or functions."[42]

The value in a software program is the functionality of the program, such as Lotus 1-2-3, Excel, WordPerfect or Word for Windows. This function was the reason why consumers purchased a program, installed it and used it on their computers.

In fact, this shift from copyright to patent law in the mid-1990s mirrors the equally important shift in the early 1980s when the courts and Congress definitively extended copyright protection to computer programs at the start of the PC Revolution. At the time, neither legal development was destined to occur by necessity, but, in retrospect, neither development was a historical accident from the perspective of the continuing success of the Digital Revolution. These two legal developments served as the fulcrums by which it was possible for inventors and innovating firms, such as Apple, Microsoft, eBay, Google, etc. to commercialize these newly created values. (See, e.g., the earlier-cited patented innovation in computer programs, properly secured to these companies, which made it possible for them to bring such values to the marketplace and to everyone's lives.)

At approximately the same time that the First Circuit and Supreme Court came to the legally correct conclusion in *Lotus v. Borland* that the functional value in the pull-down menus was not copyrightable, the Court of Appeals for the Federal Circuit expressly recognized that computer programs were patentable as a digital "machine." In its now-famous 1994 decision in *In re Alappat*,[43] the Federal Circuit ruled that a specific computer program that performed a specific and identifiable function for an end-user was not an "abstract" claim to an unpatentable idea or "algorithm."[44] To the contrary, such computer programs were patentable inventions.[45]

In essence, the Federal Circuit recognized the basic truth to which many firms in the high-tech industry owed

their existence: a computer program such as the Excel spreadsheet program "is not a disembodied mathematical concept which may be characterized as an 'abstract idea.'"[46] A computer program, such as Google's search algorithm, or a sub-program, such as an operation in Excel's spreadsheet, is the digital equivalent of "a specific machine."[47] In sum, the invention of a word processing program is the equivalent in the Digital and PC Revolutions of the invention of a mechanical typewriter in the Industrial Revolution. Similarly, an e-mail produced by the functions of a word processing program in an email program, such as Outlook or Eudora, is the digital equivalent of a physical letter written by a typewriter and mailed via the U.S. Post Office to its recipient.

Again, similar to the identification that the value in a computer program is its functionality to the end-user, the identification of the essential functional similarity between a mechanical typewriter and a word processing program is not particularly insightful or radical. As any computer programmer will tell you, the functions of a program can be performed perfectly in either software or hardware; the functional operation between the two is a distinction without a difference, except that a computer program is less costly and more efficiently sold and used by end-users. In fact, this equivalence between hardware and software is exactly what happened for the first several decades of the Digital Revolution before the invention of the integrated circuit and before the PC Revolution. And for those of us old enough to remember the very first word processors, there was not much to them beyond what an electrical typewriter could do in the 1970s and 1980s (including correct spelling errors after a word was typed and other formatting functions as well).

In sum, the functionality of binary code in a specific computer program is in principle no different from the functionality achieved in the binary logic hardwired into computer hardware. The fact that both are easily identified by firms, retailers and end-users confirms that the two can be specific, real-world and useful products. This functional equivalence between hardware and software further reflects the fact that the difference between computer programs (either in software or hardware) and the mechanical machines they replaced is itself a distinction without a difference — both have been innovative inventions deserving of protection under the patent laws.

Conclusion

The Industrial Revolution gave us patented innovation in sewing machines,[48] typewriters, and telephones, and the Digital and PC Revolutions have given us patented innovation in word processors, email and ebooks. To restrict the patent system to only the valuable inventions of the nineteenth century is to turn the patent system on its head—denying today's innovators the protections of the legal system whose purpose is to promote and secure property rights in innovation.

In the words of the Supreme Court's recent decision in *Bilski v. Kappos*,[49] patent law is a "dynamic provision designed to encompass new and unforeseen inventions."[50] As the *Bilski* Court recognized, a physical-based "machine-or-transformation test may well provide a sufficient basis for evaluating processes similar to those in the Industrial Revolution—for example, inventions grounded in a physical or other tangible form. But there are reasons to doubt whether the test should be the sole criterion for determining the patentability of inventions in the Information Age."[51]

The American patent system has succeeded because it has secured property rights in the new innovation that has come about with each new era—and it has secured the same property rights for all types of new inventions, whether in the Industrial Revolution or in the Digital Revolution. It is time to leave behind sophistical rhetoric, such as "software patent," and recognize that computer programs are valuable inventions performing very real and valuable functions for consumers the world over. This is why people from all walks of life pay money to companies like Apple, Microsoft, Dell, Cisco and many others to purchase these programs. As made clear in *Borland v. Lotus*, this is a real-world value that cannot and should not be secured by copyright. It also cannot be secured by trade secret because the functions of a program are the publicly known capabilities sought by end-users (and over which high-tech companies compete for customers). As the history of the evolution of patent protection for computer programs makes clear, this valuable innovation can be secured only by the IP regime specifically designed to secure functional value in new technological innovation —the patent system.

ENDNOTES

1 *See* Wikipedia, *Software patent debate* (as of Sep. 19, 2013), http://en.wikipedia.org/wiki/Software_patent_debate.

2 *See* Adam Mossoff, *A Century-Old Form of Patent*, N.Y. Times, Jun. 6, 2013, http://www.nytimes.com/roomfordebate/2013/06/06/can-the-human-blueprint-have-owners/a-century-old-form-of-patent.

3 *See* 35 U.S.C. § 101 (providing that "any new and useful process, machine, manufacture, or composition of matter" is patentable).

4 *See* Richard A. Posner, *Why There are Too Many Patents in America*, The Atlantic (July 12, 2013).

5 *See Ritchie v. Vast Resources, Inc. (d/b/a Topco Sales)*, 563 F.3d 1334 (Fed. Cir. 2009) (Posner, J.).

6 717 F. 3d 1269 (2013) (en banc).

7 *See* Semil Shah, Op-Ed., *The Scale, Competitiveness, And Industrial Strategies in Mobile Computing*, TechCrunch, Sep. 8, 2013, http://techcrunch.com/2013/09/08/the-scale-competitiveness-and-industrial-strategies-in-mobile-computing/ (describing vibrant, dynamic growth in the computer industry, especially in the last two years).

8 *CLS Bank*, 717 F.3d at 1276-92.

9 *Id*. at 1301.

10 *See* John Kong, *The Alice in Wonderland En Banc Decision by the Federal Circuit in CLS Bank v. Alice Corp*, IPWatchdog (May 14, 2013, 3:16 pm), http://www.ipwatchdog.com/2013/05/14/the-alice-in-wonderland-en-banc-decision-by-the-federal-circuit-in-cls-bank-v-alice-corp/id=40344/.

11 *See* MacMillan Dictionary, http://www.macmillandictionary.com/dictionary/british/potted (as of Sep. 16, 2013, 10:21 PM GMT).

12 *State St. Bank & Trust Co. v. Signature Financial Grp*., 149 F. 3d 1368 (Fed. Cir. 1998).

13 *In re Alappat*, 33 F. 3d 1526 (Fed. Cir. 1994) (en banc).

14 *Diamond v. Diehr*, 450 U.S. 175 (1981).

15 *See* Adam Mossoff, *The SHIELD Act: When Bad Economic Studies Make Bad Laws*, Center for the Protection of Intellectual Property Blog (Mar. 15, 2013), http://cpip.gmu.edu/2013/03/15/the-shield-act-when-bad-economic-studies-make-bad-laws/ (identifying how "patent troll" lacks any definition and is used non-objectively in patent policy debates).

16 *See* End Soft Patents, *Software is math* (as of Sep. 19, 2013), http://en.swpat.org/wiki/Software_is_math.

17 This characterization of computer programs as merely "mathematical algorithms" is an unfortunate byproduct of the Supreme Court's decision in *Gottschalk v. Benson*, 409 U.S. 63 (1972), in which Justice William O. Douglas described an invention of a fundamental software program for running all computers as an "algorithm." *Id.* at 65 ("A procedure for solving a given type of mathematical problem is known as an 'algorithm.' The procedures set forth in the present [patent] claims are of that kind."). Justice Douglas thus concluded that the invented computer program was an unpatentable abstract idea:

> It is conceded that one may not patent an idea. … The mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is

affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.

Id. at 71-72. This was an unfortunate misinterpretation of the nature of computer programs as such, and it has caused much confusion in patent law about both computer programs and what makes them patentable inventions. *CLS Bank* simply represents the nadir of this confusion. What is notable, as is made clear in this essay, is that this confusion about the nature of computer programs in 1972 was perhaps understandable, if only because the PC Revolution had not yet occurred and thus it was much harder for judges to understand what made computer programs valuable as separate (patentable) inventions from the computer hardware on which they ran.

18 *See* Gene Quinn, *Groklaw Response: Computer Software is Not Math*, IPWatchdog (Dec. 15, 2008, 6:30 am), http://www.ipwatchdog.com/2008/12/15/computer-software-is-not-math/.

19 Carolyn Y. Johnson, *A talk with Mario Livio – Is Mathematics the Language of the Universe*, Boston Globe, Feb. 8, 2009, http://www.boston.com/bostonglobe/ideas/articles/2009/02/08/a_talk_with_mario_livio/.

20 Timothy B. Lee, *Software is Just Math*, Forbes, Aug. 11, 2011, http:/www.forbes.com/sites/timothylee/2011/08/11/software-is-just-math-really/.

21 U.S. Gov't Accountability Office, GAO-13-465, INTELLECTUAL PROPERTY: Assessing Factors That Affect Patent Infringement Litigation Could Help Improve Patent Quality 21 (2013), http://www.gao.gov/products/GAO-13-465.

22 *See Patent Statistics in the GAO Report*, High Tech Intellectual Property Legal Blog (Sep. 18, 2013), http://blog.hiplegal.com/2013/09/gao_softwarepatents/("The problem, of course, is that there are no 'exclusively software' classes. So if an entire patent class is counted, it is extremely likely to include non-software cases as well."). Wegner and others also claim that the GAO actually made an outright error in its counting methodology. *See* Hal Wegner, *GAO Patent Litigation Report (con'd): "[P]atents related to software ma[ke] up more than half of all … patents*, LAIPLA (Aug. 2, 2013), http://www.laipla.net/gao-patent-litigation-report-cond-patents-related-to-software-make-up-more-than-half-of-all-patents/ ("The GAO authors apparently counted 20,000 software patents instead of 2,000 under the methodology at p.12 n.27 (explaining Figure 1). Thanks to Greg Aharonian for sharing this information with the patent community."); http://www.global-patent-quality.com/GRAPHS/SoftElec.htm (reporting Greg Aharonian's statistics on issued patents that show that even the 2,000 number is almost twice the actual rate of issuance of "software" patents).

23 *See* Wikipedia, *Software* (as of Sep. 19, 2013), http://en.wikipedia.org/wiki/Software.

24 *See* John Markoff, *Creating a Giant Computer Highway,* N.Y. Times (1990), http://www.nytimes.com/1990/09/02/business/creating-a-giant-computer-highway.html.

25 *See* T.R. Reid, *The Chip: How Two Americans Invented the Microchip and Launched a Revolutio*n 76-80 & 91-95 (2001).

26 *See* Wikipedia, *Digital Equipment Corporation* (as of Sep. 19, 2013), http://en.wikipedia.org/wiki/Digital_Equipment_Corporation.

27 Bill Gates has written: "An inventor, scientist, and entrepreneur, Ken Olsen is one of the true pioneers of the computing industry. He was also a major influence in my life and his influence is still important at Microsoft through all the engineers who trained at Digital and have come here to make great software products." Chloe Albanesius, *Computing Pioneer Ken Olson Dead at 84*, PC Magazine, Feb. 8, 2011, http://www.pcmag.com/article2/0,2817,2379648,00.asp.

28 *See* Joelle Tessler, *Kenneth Olsen, Pioneering Founder of Computer Company, Dies at 84*, Wash. Post, Feb. 9, 2011, http://www.washingtonpost.com/wp-dyn/content/article/2011/02/09/AR2011020906305.html.

29 Timothy B. Lee, *The Supreme Court Should Invalidate Software Patents*, Forbes, Jul. 28, 2011, http://www.forbes.com/sites/timothylee/2011/07/28/the-supreme-court-should-invalidate-software-patents/.

30 *See* National Commission on New Technological Uses of Copyrighted Works, Final Report 82 (1979); Copyright Office Circular 31D (Jan. 1965).

31 *See, e.g.,* Allen W. Puckett, *The Limits of Copyright and Patent Protection for Computer Programs*, 16 Copyright L. Symp. 81, 104-05 (1968) (recognizing that there is limited copyright protection for some aspects of computer programs but that "[s]ource programs embodied in punch cards or magnetic tape present a doubtful case"); Pauline Wittenberg, Note, *Computer Software: Beyond the Limits of Existing Proprietary Protection Policy*, 40 Brooklyn L. Rev. 116, 117-18 (1973) ("With respect to computer software, such questions [about patent or copyright protection] have been under discussion in both legal and trade journals and in the courts for nearly a decade; no clear answers have emerged.").

32 *Compare Data Cash Systems, Inc. v. JS&A Group, Inc.*, 480 F. Supp. 1063 (N.D. Ill. 1979) (holding object code is not copyrightable) *and Tandy Corp. v. Personal Micro Computers, Inc.*, 524 F.Supp. 171 (N.D. Cal. 1981) (holding object code in ROM is copyrightable). *See also Synercom Tech., Inc. v. Univ. Comp. Co.*, 462 F. Supp. 1003, 1014 (N.D. Tex. 1978) (holding software code "formats" is not copyrightable).

33 Pub. L. No. 96-517, 94 Stat. 3015, 3028 (1980).

34 *See* Wikipedia, *Egghead Software* (as of Sep. 19, 2013), http://en.wikipedia.org/wiki/Egghead_Software.

35 Nathan Mryhvold, *Invention: The Next Software*, Intellectual Ventures, at 5 (2006), http://www.intellectualventures.com/assets_docs/Invention_Next_Software_Transcript_2006_Speech.pdf.

36 Robert R. Sachs, *Applying Can Openers to Real World Problems: The Failure of Economic Analysis Applied to Software Patents*, Bilski Blog (Aug. 13, 2013), http://www.bilskiblog.com/blog/2013/08/applying-can-openers-to-real-world-problems-the-failure-of-economic-analysis-applied-to-software-pat.html.

37 *See Baker v. Seldon*, 101 U.S. 99, 104 (1879) ("[T]he teachings of science and the rules and methods of useful art have their final end in application and use; and this application and use are what the public derive from the publication of a book which teaches them. But as embodied and taught in a literary composition or book, their essence consists only in their statement. This alone is what is secured by the copyright."); *Morrisey v. Proctor & Gamble Co.*, 379 F.2d 675, 678 (1st Cir. 1967) ("Copyright attaches to form of expression ….").

38 *See Baker*, 101 U.S. at 102 ("[N]o one would contend that the copyright of the treatise would give the exclusive right to the art or manufacture described therein. … That is the province of letters-patent, not copyright. The claim to an invention or discovery of an art or manufacture … can only be secured by a patent from the government.").

39 49 F.3d 807 (1st Cir. 1995), *aff'd by an equally divided Court*, 516 U.S. 233 (1996).

40 *Lotus Dev. Corp. v. Borland Int'l, Inc.*, 516 U.S. 233 (1996).

41 *Lotus*, 49 F.3d at 815.

42 *Qualitex Co. v. Jacobsen Products Co., Inc.*, 514 U.S. 159, 164 (1995); *Elmer v. ICC Fabricating*, 67 F.3d 1571, 1580 (Fed. Cir. 1995) ("patent law, not trade dress law, is the principal means for providing exclusive rights in useful product features"). *See also Baker,* 101 U.S. at 102 ("[T]he exclusive right to the art or manufacture …. is the province of letters-patent, not copyright.").

43 33 F. 3d 1526 (Fed. Cir. 1994) (en banc).

44 *Id.* at 1545.

45 *Id.*

46 *Id.* at 1544.

47 *Id.*

48 *See* Adam Mossoff, *The Rise and Fall of the First American Patent Thicket: The Sewing Machine War of the 1850s*, 53 Ariz. L. Rev. 165 (2011).

49 130 S. Ct. 3218 (2010).

50 *Id.* at 3227.

51 *Id.*

ABOUT THE AUTHOR

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Introduction and Background from

DEBUGGING SOFTWARE'S SCHEMAS

Kristen Osenga[*]

INTRODUCTION

In computer terminology, a schema is a diagram or model used to describe structures for containing and processing data.[1] For example, a database schema may include information about the various fields of the database, the types of data each field may contain, and how the fields may be related.[2] Flawed schema in the computer world potentially results in a bug – an error that results in a computer program or system producing an incorrect result, acting in unexpected ways, or shutting down altogether.[3] In cognitive theory, a schema is a structure or framework that helps organize and interpret information.[4] While cognitive schemas are generally useful,

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[*] Professor of Law, University of Richmond School of Law. I would like to thank Michael Risch, Jim Gibson, Lisa Larrimore Ouellette, and Cynthia Ho for their helpful comments, as well as the members of the George Washington University Law School Law Review and participants at the "Cracking the Code: Ongoing Section 101 Patentability Concerns in Biotechnology and Computer Software" symposium.

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[1] *See, e.g.,* "schema," *available at* http://www.techterms.com/definition/schema.

[2] See id.

[3] *See, e.g.,* "bug," *available at* http://www.techterms.com/definition/bug.

[4] *See, e.g.,* Martha Augoustinos & Iain Walker, SOCIAL COGNITION: AN INTEGRATED INTRODUCTION 32 (1995) ("A schema is conceptualized as a mental structure which contains general expectations and knowledge of the world." These structures are used to "select and process incoming information from the social environment."); Ronald Chen & Jon Hanson, *Categorically Biased: The Influence of Knowledge Structures on Law and Legal Theory*, 77 S.CAL. L. REV. 1106, 1131 (2004) ("Categories and schemas are critical building blocks of the human cognitive process. They allow humans to process or at least cope with the infinite amount of information in their environs.").

allowing efficient processing of information, they too can lead to incorrect results, unexpected behaviors, or system shutdowns. This erroneous decision making may be due to cognitive biases, such as confirmation bias or stereotyping.[5] These two worlds – computer science and cognitive science – have collided at the intersection of eligibility for patent protection of software and computer-related inventions; unfortunately, the resulting system is in dire need of debugging.[6]

Bugs in the software patent framework are causing problems, largely manifested by a lack of organization and guidance regarding the patent eligibility of software and computer-related inventions. Whether, and to what extent, these inventions are eligible for patenting is a complete toss-up under current law and this lack of certainty is having a widespread effect on the entire patent system.[7] Judicial opinions about software patent eligibility produce unexpected results,[8] legislative proposals that address the

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[5] *See, e.g.,* Sara Gordon, *Through the Eyes of Jurors: The Use of Schemas in the Application of 'Plain-Language' Jury Instructions*, 64 HASTINGS L.J. 643, 657 (2013) (schemas and confirmation bias); Chen & Hanson, *supra* note ___, at 1231 (schemas and stereotyping).

[6] *See, e.g,* "debug," *available at* http://www.techterms.com/definition/debug (debugging is the elimination of errors in computer programs, ideally before releasing the program to the public).

[7] *See, e.g.,* Donald S. Chisum, *Weeds and Seeds in the Supreme Court's Business Method Patents Decision: New Directions for Regulating Patent Scope*, 15 LEWIS & CLARK L.REV. 11, 14 (2011) (noting that the software patent framework, as currently stands "can lead to subjectively-derived, arbitrary, and unpredictable results. This uncertainty does substantial harm to the effective operation of the patent system.")); Michael Risch, *Forward to the Past*, CATO SUPREME CT. REV. 333, 362-368 (discussing implications of Supreme Court patent eligibility jurisprudence). *See also* Section I.B., *infra*.

[8] *See* Section II.A., *infra*.

topic may produce incorrect results,[9] and, as some commentators hope, the software patent system is in danger of shutting down altogether.[10]

The frameworks that are currently influencing decision making about software patents include the analysis that software patents are generally bad (the bad patent schema) and that software patent holders are problematic (the troll schema).[11] There are two problems with these frameworks: first, the bad patent schema and the troll schema have been created through various cognitive biases, resulting in flaws, and second, these two schemas that are helping frame the issue for decision makers are unlikely the right structure to answer the underlying question about whether patent protection should be available for software and computer-related inventions.

While efficient information processing via schema and other cognitive biases has its place, there are times when objective, deliberate, and careful consideration of an issue is more appropriate.[12] A large number

[9] *See, e.g.,* Timothy B. Lee, *Software patent reform just died in the House, thanks to IBM and Microsoft*, WASHINGTON POST, The Switch (Nov. 20, 2013) (*available at* http://www.washingtonpost.com/blogs/the-switch/wp/2013/11/20/software-patent-reform-just-died-in-the-house-thanks-to-ibm-and-microsoft/) (citing a letter signed by IBM, Microsoft, and others, claiming that the reform measures "could harm U.S. innovators by unnecessarily undermining the rights of patent holders").

[10] Some are not shy about their willingness to kill software patents. See, e.g., Colleen V. Chien, *Pondering Patents: First Principles and Fresh Possibilities, Institute for Intellectual Property and Information Law Symposium: Article: Reforming Software Patents*, 50 HOUS. L. REV. 325, 352 (2012) (noting that abolishing software patents "has enormous popular appeal" as well as "historical and recent precedent."). Others take a more measured approach. See, e.g, James Bessen & Michael J. Meurer, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, & LAWYERS PUT INNOVATORS AT RISK 235-53 (2008) (allowing for reform of software patents but freely accepting exclusion of software patents if reform is unsuccessful).

[11] *See* Section ___, *infra*.

[12] *See* Cynthia Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 SAN DIEGO L.REV ___, 13 (forthcoming 2014), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2318820. (noting that quick and intuitive decision making is useful when avoiding a car accident, while at other times, deliberation is a better course of action).

of software patent applications are filed each year[13] and it is estimated that hundreds of thousands of patents covering software and computer-related inventions are in force.[14] Whether software and computer-related inventions are patent eligible is far too important a question to rely on biased or incorrect schemas. Before the conversation goes any further, we should try to debug the software patent schemas. To be sure, it is not possible to fully debug the system; cognitive biases can never be completely eliminated and some level of shortcut is desirable when assessing the vast number of patent applications filed each year.[15] But with awareness of these bugs in the system as we consider software and computer-related inventions, we should be better able to make a principled, objective decision about their patent eligibility.[16]

I. THE STATE OF SOFTWARE PATENTS

A discussion of the current state of patent eligibility for software and computer-related inventions naturally must begin with a definition of what is even meant by "software." After defining software, the present jurisprudence, such as it is, of patent eligibility for these inventions is reviewed.

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[13] Although the United States Patent and Trademark Office (PTO) has no classification specifically directed towards software and computer-related inventions, it does try to quantify how many "software" patents issued each year, stating that as many as one-half of the nearly 250,000 patents issued annually are directed towards software inventions. See United States Government Accountability Office, Intellectual Property: Assessing Factors That Affect Patent Infringement Litigation Could Help Improve Patent Quality, fig. 1, available at http://www.gao.com/products/GAO-13-465 (2013).

[14] *See, e.g.,* Mark A. Lemley, *Robert W. Kastenmeier Lecture: Software Patents and the Return of Functional Claiming*, 2013 WIS. L.REV. 905, 928.

[15] *See, e.g.,* U.S. Patent Statistics Chart, Calendar Years 1963-2012 (*available at* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm). In 2012, a total of 542,815 patent applications were filed.

[16] *See* Ian Weinstein, *Don't Believe Everything You Think: Cognitive Bias in Legal Decision Making*, 9 CLINICAL L. REV. 783, 792 (2003). *See also* Troy Paredes, *Corporate Decisionmaking: Too Much Pay, Too Much Deference: Behavioral Corporate Finance, CEOs, and Corporate Governance*, 32 FLA. ST. U.L. REV. 673, 739 (2005) ("Making [decision makers] aware of their cognitive tendencies and how they process and interpret information (that is, teaching [decision makers] how they deviate from perfect rationality) can mitigate cognitive bias.").

Excerpt - *Debugging Software's Schemas*

A. What is Software?

Defining software is no easy task. One potential starting point, given that we are discussing technology, would be to seek a technical definition; for example, the Institute of Electrical and Electronics Engineers (IEEE) defines software as "computer programs, procedures, and possibly associated documentation and data pertaining to the operation of a computer system."[17] Another option would be to start with a legal definition for software; after all, we are considering legal rights in the form of a patent. However, the United States Patent & Trademark Office (PTO) does not have a specific classification for "software" patents. Studies of "software patents" include patents on methods generally implemented by software or software-using devices.[18] To this end, researchers often identify software patents by two main methods – keyword searches and PTO technology classes, such as data processing (PTO technology classes 700-707 and 715-17).[19]

One particular difficulty in defining software is that, due to the uncertain state of patent eligibility for software and computer-related inventions, patent attorneys often draft claims to obscure the true nature of

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[17] *See* Institute of Electrical and Electronics Engineers (IEEE), STANDARD GLOSSARY OF SOFTWARE ENGINEERING TERMINOLOGY (STD. 610.12-1990), at 66 (Sept. 28, 1990).

[18] *See* Sebastian von Engelhardt, *The Economic Properties of Software*, (Jena Econ. Research Papers, Working Paper No. 2008-045, 2008), available at http://hdl.handle.net/10419/25729.

[19] *See* James Bessen, *A Generation of Software Patents*, 18 B.U. J. SCI. & TECH. L. 241, 251 (2012). Bessen, for example, used PTO classes for data processing (700-707 and 715-17) and other classes that are reliant on software, e.g., (341 – coded data generation, 345 – computer graphics processing, 370 – multiplex communication, 375 – digital communications, 380 – cryptography, 381 – audio signal processing, 382 – image analysis, 726 – information security, and 902 – electronic funds transfer). *See id.* at 252 (based on PTO classifications as of 12/28/2010).

There are other methods that have been used to categorize "software patents." For example, Stuart J.H. Graham & David C. Mowery use International Patent Classification (IPC) class/subclass/groups. *Intellectual Property Protection in the U.S. Software Industry*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY (Wesley M. Cohen & Stephen A. Merrill eds., 2003) 219, 232. Various methods of defining "software patents" have been compared by Anne Layne-Farrar, *Defining Software Patents: A Research Field Guide* (2006), *available at* http://ssrn.com/abstract=1818025.

the patented invention.[20] To avoid this, one method is to define "software" patents as widely inclusive. For example, a recent patent reform bill, popularly known as the SHIELD Act of 2012, defines software as "any process that could be implemented in a computer regardless of whether a computer is specifically mentioned in the patent" as well as "any computer system that is programmed to perform a process."[21] A "computer" is similarly broadly defined as an "electronic, magnetic, optical, electrochemical, or other high-speed data processing device performing logical, arithmetic, or storage functions."[22]

Another difficulty in defining software is that "software" is an ever-changing target. The shape and format of software keeps evolving as the machines for which it is written also progress – whereas room-sized computers ran early software using shift registers, now surprisingly powerful software can run on a device that fits in your pocket (or smaller).[23] Software is made by software companies, Internet and social media companies, hardware manufacturers, non-software firms, and even software users.[24] And while there is software qua software, there is also software in your hybrid car that switches from gasoline power to electric power, software in your washing machine that adjusts the wash cycle depending on how dirty the clothes are, software in your cell phone that knows that it is

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[20] *See* Chien, *supra* note ___, at 354; Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CALIF. L.REV. 1, 9 (unveiling the "doctrine of the magic words," the practice of drafting software patent claims to appear to cover something else).

[21] *See* Saving High-Tech Innovators from Egregious Legal Disputes Act of 2012, H.R. 6425, 112th Cong., § 285A(b)(1)(3).

[22] *See id.*

[23] *See, e.g.,* Clayton Christensen et al., *The Great Disruption*, FOREIGN AFF., Mar.-Apr. 2001, 80, 83-85 (discussing the evolution of computers from 1946 and the room-sized ENIAC to modern day personal computers). Obviously in the time since the Christensen article was written, computers have evolved even further. *See, e.g.,* John Markoff, *Researchers Build a Working Carbon Nanotube Computer*, N.Y. TIMES, Science (Sept. 25, 2013) (noting that the "shrinking of transistor size over the last half-century has been important because it has significantly lowered the cost of computing, making it possible to build ever more powerful computers that are faster and cheaper, and consume less power with each generation" and highlighting a new advance using nanotechnology that will shrink transistor size even more).

[24] *See*, Seltzer, *supra* note ___ at 947.

night and turns off the ringer, and so on.[25] Software may not even run on the device in question, but instead function as some form of client-server application.[26] The reality is that software is everywhere.[27]

B. The Software Patent Mess

If defining software is a difficult task, untangling the fiasco that is the law surrounding patent eligibility for software and computer-related inventions is nearly impossible. Neither the U.S. Court of Appeals for the Federal Circuit nor the Supreme Court has provided any solid framework for determining the level of patent protection, if any, available for these inventions. Without guidance, patent eligibility decisions of the Patent Office, as well as the district and appellate courts, are all over the board.[28] It is no wonder, then, that there are calls to eliminate patent protection

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[25] *See, e.g.*, Peter Fairley, *Software Looks at the Road Ahead to Boost Hybrid-Car Efficiency*, IEEE SPECTRUM (Feb. 3, 2009) (*available at* http://spectrum.ieee.org/computing/software/software-looks-at-the-road-ahead-to-boost-hybridcar-efficiency) (discussing control algorithms in hybrid cars that "plan how and when to use stored battery power so as to burn as little gasoline as possible"); Michael Kanellos, *The Sleeping TV, LED Lights and a Washing Machine that Sees Sweat Stains: The Latest from Japan*, GREEN TECH MEDIA (Oct. 6, 2009) (*available at* http://www.greentechmedia.com/articles/read/the-sleeping-tv-led-lights-and-a-washing-machine-that-sees-sweat-stains-the) (touting a washing machine that detects how dirty clothes are); Justin Shillock, *Silent Time Automatically Silences Your Android Phone Based on Time of Day*, LIFEHACKER (Feb. 18, 2011) (*available at* http://lifehacker.com/5764363/silent-time-automatically-silences-your-android-phone-based-on-time-of-day) (describing a phone app that allows you to silence the ringer at certain times).

[26] *See* Wendy Seltzer, *Software Patents and/or Software Development*, 78 BROOKLYN L.REV. 929, 954 (2013) (noting that technology has changed even further and client-client-and-multiple-servers is more dominant than client-server).

[27] *See* Paul Krill, *Microsoft Exec: The World Runs on Software*, INFOWORLD (Apr. 12, 2010), http://infoworld.com/d/developer-world/microsoft-exec-the-world-runs-software-391 (*last visited* Dec. 18, 2013) ("Everything is powered by software and 'developers are the ones who make it all happen.'").

[28] For an example of conflicting court opinions, compare *CLS Bank Int'l v. Alice Corp.*, 685 F.3d 1341 (Fed. Cir. 2012), *reh'g en banc granted, opinion vacated,* 484 F. App'x 559 (Fed. Cir. 2012), *aff'd en banc*, 717 F.3d 1269 (Fed. Cir. 2013) with *Bancorp Servs. V. Sun Life Assurance Co.*, 687 F.3d 1266 (Fed. Cir. 2012). At the agency level, compare *SAP Am. Inc. v. Versata Development Group, Inc.*, CBM 2012-00001 (PTAB, June 11, 2013), with *Apple Inc. v. Sightsound Techs. LLC*, CBM 2013-00019 (PTAB, Oct. 8, 2013).

altogether for software and computer-related inventions simply to avoid the chaos.[29]

The statute that defines patent-eligible subject matter is deceptively simple; its interpretation at the hands of the courts is anything but simple. Section 101 of the Patent Act permits patenting of "any new and useful process, machine, manufacture, or composition of matter."[30] This statute has long been construed broadly as encompassing "anything under the sun that is made by man," excluding only "laws of nature, physical phenomena, and abstract ideas."[31]

The battle line for the patent eligibility of software and computer-related inventions is in the definition of "abstract idea," or more precisely, when an idea is too abstract to warrant patent protection. As Judge Linn of the Federal Circuit has recently stated:

> The abstractness of the 'abstract ideas' test to patent eligibility has become a serious problem, leading to great uncertainty and to the devaluing of inventions of practical utility and economic potential. . . . This court has . . . attempted to define 'abstract ideas,' explaining that 'abstract ideas constitute disembodied concepts or truths which are not 'useful' from a practical standpoint standing alone, i.e., they are not 'useful' until reduced to some practical application.' More recently, this court explained that the 'disqualifying characteristic' of abstractness must exhibit itself 'manifestly' 'to override the broad statutory categories of patent eligible subject matter.' Notwithstanding these well-intentioned efforts . . . the dividing line between inventions that are directed to patent ineligible abstract ideas and those that are not remains elusive. Put simply, the

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[29] *See, e.g.*, Joshua D. Sarnoff, *Patent-Eligible Inventions after* Bilski*: History & Theory*, 63 HASTINGS L.J. 53, 106-07 (2011) (calling for categorical eligibility rules as superior to other means of gatekeeping); Brian J. Love, *Why Patentable Subject Matter Matters for Software*, 81 GEO. WASH. L.REV. ARGUENDO 1, 3 (2012) (*available at* http://www.gwlr.org/wp-content/uploads/2012/09/Love_Arguendo_81_1.pdf) (noting that while eligibility is not the best solution for the software patent problem is not the best solution, it is "the only defensive mechanism left").

[30] 35 U.S.C. § 101.

[31] *See* Diamond v. Chakrabarty, 447 U.S. 303, 308-309 (1980).

> problem is that no one understands what makes an idea 'abstract.'[32]

The fact that "no one understands what makes an idea 'abstract'" could be related to the historical path patent eligibility jurisprudence has taken. The course leading to the software patent mess is no less of a "murky morass" than the state of the jurisprudence itself.[33]

In the last few years, there has been a discourse between the Federal Circuit and the Supreme Court in an attempt to define an "abstract idea" that renders an invention ineligible for patenting. Despite the flurry of activity in recent years, the path dates back to the 1970s and early 1980s when the Supreme Court provided a relatively unworkable standard in a trilogy of cases concerning early software inventions ("the trilogy cases") – *Gottschalk v. Benson*, *Parker v. Flook*, and *Diamond v. Diehr*.[34] The resulting standard, to the extent there was one, was that claims including algorithms were suspect as being "abstract ideas" and that algorithms per se were not eligible for patenting.[35] The courts used, and struggled with, this standard for nearly a quarter century.

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[32] CLS Bank Int'l v. Alice Corp. Pty. Ltd., 685 F.3d 1341, 1348-49 (Fed. Cir. 2012) (internal citations omitted), *vacated for en banc reh'g*, CLS Bank Int'l v. Alice Corp. Pty. Ltd., 2012 U.S. App. LEXIS 20906 (Fed. Cir. 2012).

The very "utility and economic potential" of software and computer-related inventions is why this question is so important. Further, as noted by Judge Rader, in *Research Corp. Techs. V. Microsoft Corp.*, the whole point of software is to provide an implementation of an idea designed to reach a *commercially valuable end…*the exact opposite of abstract. *See* Research Corp. Techs., Inc. v. Microsoft Corp., 627 F.3d 859, 69 (Fed. Cir. 2010) ("Inventions with specific applications or improvements to technologies in the market-place are not likely to be [deemed abstract and unpatentable]."). *See also* Dina Roumiantseva, *Note: The Eye of the Storm: Software and the Abstract Idea Doctrine in* CLS Bank v. Alice, 28 BERKELEY TECH. L.J. 569, 579 (2013).

[33] *See* MySpace, Inc. v. Graphon Corp., 672 F.3d 1250, 1259-60 (Fed. Cir. 2012).

[34] *See* Gottschalk v. Benson, 409 U.S. 63 (1972); Parker v. Flook, 437 U.S. 584 (1978); Diamond v. Diehr, 450 U.S. 175 (1981).

[35] *See, e.g.,* Kevin Emerson Collins, *Patent Law's Functionality Malfunction and the Problem of Overbroad, Functional Software Patents*, 90 WASH. U. L.REV. 1399, 1467-68 (2013).

Then, in the late 1990s, the Federal Circuit decided a set of cases widely believed to have opened the doors of the Patent Office to software and business method patents[36] – *State Street Bank & Trust Co. v. Signature Financial Group, Inc.* and *AT&T v. Excel Communications, Inc.*[37] In these cases, the Federal Circuit implemented the "useful, concrete, and tangible result" test for "abstract ideas" – if an invention produced a useful, concrete, and tangible result, it was not abstract and could be patented.[38] After some years, the Supreme Court began to signal some discomfort with the viability of the "useful, concrete, and tangible result" test, pointing backwards to the trilogy cases but providing little additional guidance.[39]

After a turn, the *en banc* Federal Circuit implemented a new test to determine whether an invention was merely an "abstract idea and thus not eligible for patent protection. This new test, the "machine or transformation" test allowed for patenting of inventions that either 1) were tied to a particular machine or apparatus or 2) transformed an article to a different state or thing.[40] The Supreme Court immediately took issue with this new test, indicating that it should not be used as the "sole test" for patent eligibility.[41] Instead, the Court again fell back on its precedent, noting that the Court "need not define further what constitutes a patentable 'process,' beyond . . . looking to the guideposts in [the trilogy cases:] *Benson*, *Flook*, and *Diehr*."[42] This proved less than helpful.[43]

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[36] *See, e.g,* Jonathan M. Barnett, *Property as Process: How Innovation Markets Select Innovation Regimes*, 119 YALE L.J. 384, 408 n. 55 (explaining how *AT&T* allowed for patentability of software qua software), 415-16 (2009) (explaining how the *State Street* decision "explicitly rejected the historical exclusion of business method patents"). Other scholars disagree with this narrative. *See* Risch, *supra* note ___ at 341 (stating that *Diehr* opened the door to software patenting, well before *State Street*).

[37] *See* State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368 (Fed. Cir. 1998); AT&T v. Excel Communications, Inc., 172 F.3d 1352 (Fed. Cir. 1999).

[38] *See* State Street Bank, 149 F.3d at 1373; AT&T, 172 F.3d at 1360-61 (applying *State Street*'s "useful, concrete, and tangible result" test to software-related inventions).

[39] *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 584 U.S. 124, 134-136 (2006) (Breyer, J., dissenting).

[40] *See* In re Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008) (en banc).

[41] *See* Bilski v. Kappos, 130 S.Ct. 3218, 3221 (2010).

[42] *See id.* at 3222.

Lacking a coherent framework or constructive leadership from the Supreme Court, the Federal Circuit continued to flounder, trying to apply vague precedent to today's technology, while navigating the "swamp of verbiage"[44] that is the courts' precedent on software patenting and facing an increasingly hostile public outcry against patent protection for these types of inventions.[45] Additional Supreme Court opinions about patent eligible subject matter issued but did not provide any additional guidance for defining "abstract ideas."[46] And then the Federal Circuit published its 2013 *en banc* opinion in *CLS Bank International v. Alice Corp. Pty*. In trying to provide clarity about patent protection for software and computer-related inventions, the Federal Circuit's decision instead included seven separate opinions, representing at least three distinct viewpoints on the subject.[47] In fact, the only thing a majority of the court agreed on was that the invention in question was not eligible for patenting; there was no agreement as to

[43] *See, e.g.,* Kevin Emerson Collins, *supra* note ___, at 1458 (describing how, in *Bilski*, the Supreme Court "held that its earlier (and difficult to parse) opinions" in the trilogy cases were the ultimate test and that the Court's holding was based on rhetoric, rather than reason, from those cases).

[44] *See* MySpace, Inc.., 672 F.3d at 1259-60.

[45] For one boisterous, although not unrepresentative, example of the public's outcry against software patents, consider Mark Cuban, who established the "Mark Cuban Chair to Eliminate Stupid Patents." Cuban calls software patents "'stupid' patents that should have been completely abolished or at least have a shorter legal life." *See, e.g.,* Efrat Kasznik, *Troll Slayer: Can Mark Cuban cure the U.S. Patent System?*, VENTUREBEAT (Feb. 10, 2013) (*available at* http://venturebeat.com/2013/02/09/troll-slayer-can-mark-cuban-cure-the-u-s-patent-system/patenttroll/).

[46] *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S.Ct. 2107 (2013) (directed more particularly to what is ineligible as a "natural phenomena") and Mayo Collaborative Services v. Prometheus Labs., Inc., 132 S.Ct. 1289 (2012) (finding inventions that are "well-understood, routine, conventional activity, previously engaged in by researchers in the field" to be ineligible for patenting).

[47] *See* CLS Bank Int'l v. Alice Corp. Pty, 717 F.3d 1269 (Fed. Cir. 2013) (*en banc*).

why.[48] At the annual meeting of the American Intellectual Property Association in May 2013, Chief Judge Rader noted that the failure of the Federal Circuit to provide guidance about software patentability in the *CLS Bank* case was the "greatest failure" in his judicial career.[49]

The Supreme Court granted certiorari in the *CLS Bank* case on December 6, 2013.[50] It is unclear whether the Court's treatment of patent eligibility for software and computer-related inventions will provide any clarity to the jurisprudential mess. More likely, unless the bugs in software's schemas are addressed first, the opinion of the Court will be more of the same.

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[48] *See id. See also* Mike Masnick, *Supreme Court to Hear Key Case on Software Patents that Appeals Court Couldn't Figure Out*, TECHDIRT (Dec. 6, 2013) (*available at* http://www.techdirt.com/articles/20131206/15334125492/supreme-court-to-hear-key-case-software-patents-that-appeals-court-couldnt-figure-out.shtml) (noting that the Federal Circuit opinion "was one of the biggest judicial messes you'll ever see" with "135 pages of different judges all disagreeing with each other" and "only one single paragraph that the court agreed on").

[49] *See, e.g.,* Brian Mahoney, *Software Patent Ruling a Major Judicial Failure*, LAW 360, *available at* http://www.law360.com/articles/482264/print?section=ip (last visited 10/29/2013).

[50] *See* Alice Corp. Pty. Ltd. V. CLS Bank Int'l, 717 F.3d 1269 (Fed. Cir. 2013), cert. granted, 82 U.S.L.W. 3346 (U.S. Dec. 6, 2013) (No. 13-298).

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Editorial

Preliminary Thoughts on *Mayo v. Prometheus*: The Implications for Biotechnology

By CHRISTOPHER M. HOLMAN*

On March 20, 2012, the Supreme Court issued its much-anticipated decision in *Mayo v. Prometheus*,[1] a case addressing the patent eligibility of personalized medicine and diagnostic methods. The Federal Circuit had upheld Prometheus' claims as patent eligible,[2] relying on a relatively permissive interpretation of the Supreme Court's 2010 *Bilski*[3] decision. But in *Mayo*, an obviously displeased Supreme Court reversed, declaring all of the claims patent ineligible in a unanimous decision authored by Justice Breyer that harkens back to his dissent in *LabCorp v. Metabolite*.[4] Breyer's decision emphasizes the gatekeeper role of §101 and the recently reinvigorated patent-eligibility doctrine in guarding against the danger of "too much patent protection." At this point, the implications for biotechnology are far from clear and could depend on how the Federal Circuit decides the closely related case of *Association for Molecular Pathology v. Myriad Genetics*.[5] On March 26, as we go to press for this issue, the Supreme Court granted petition for *certiorari* in *Myriad*, and, in a brief written decision, sent the case back to the Federal Circuit to reconsider in light of its most recent pronouncements in *Mayo*.[6]

To begin with, although the Supreme Court's *Mayo* decision does include provocative language that might be read as rendering patent ineligible much of the innovation that occurs in biotechnology, including drug method-of-treatment claims, I believe that in fact, the decision will be interpreted more narrowly, and in a manner that maintains patent eligibility for the majority of biotechnology and pharmaceutical inventions that had been considered patent eligible prior to *Mayo*. Unfortunately, however, the language and tenor of the decision creates substantial uncertainty with respect to the patent eligibility of a large number of issued patent claims.

Clearly, the effect of *Mayo* will be felt most keenly with respect to diagnostics and personalized medicine. The identification and validation of clinically significant biomarkers will be critical in bringing to fruition the promise of the next-generation diagnostics and personalized medicine; however, in the wake of *Mayo,* it is unclear whether effective patent protection will be available to adequately incentivize the necessary research. The most direct way of patenting this important class of innovation is by means of method claims of the sort held to be patent ineligible in *Mayo* and *Myriad*.[7] Diagnostic innovators will no doubt continue to seek patent protection, but they will need to re-think their claiming strategies; and, at the very least, the Supreme Court's opinion in *Mayo* has made their task more challenging and uncertain.

Prometheus Labs' patents were based on the discovery that the safety and efficacy of certain thiopurine drugs could be improved by monitoring the concentration of metabolites of the drug in a patient's body and modifying the amount of drug administered to the patient when the concentration was found to either exceed or fall short of certain thresholds. The claims recite methods that include steps of determining the concentration of a specific drug metabolite in

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[1] *Mayo Collaborative Services dba Mayo Medical Laboratories v. Prometheus Laboratories, Inc.*, 566 U.S. ___, (Dkt. No. 10-1150); *available at* www.supremecourt.gov/opinions/11pdf/10-1150.pdf

[2] *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 628 F.3d 1347 (Fed. Cir. Dec. 17, 2010); *available at* www.cafc.uscourts.gov/images/stories/opinions-orders/08-1403.pdf

[3] *Bilski v. Kappos*, 561 U.S. __, 130 S.Ct. 3218 (June 28, 2010).

[4] *Laboratory Corp. of America Holdings dba Labcorp v. Metabolite Laboratories, Inc*., 548 U.S. 124 (June 22, 2006).

[5] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc*. (Sup. Ct. Dkt. No. 11-725).

[6] *Available at* www.supremecourt.gov/orders/courtorders/032612zor.pdf

[7] *Ass'n For Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. July 29, 2011).

a patient's body, and being informed that, if the value falls outside the thresholds, the dosage of the drug should be modified. Some of the claims also included a step of administering the drug to the patient prior to determining the concentration of metabolites.

The standard for patent eligibility, at least in the abstract, has for many years been well established by Supreme Court precedent. The Court has repeatedly held that any product or process "made by man" is patent eligible, so long as the patent claim does not "recite" or "embody" a fundamental principle, such as an abstract idea or natural phenomenon. Specific applications of fundamental principles are patent eligible—indeed, it is difficult to imagine an invention that is not to some extent based on fundamental principles. For example, the Federal Circuit held Prometheus Labs' claims to be specific applications of the correlation between metabolite concentration and optimal dosage, and hence patent eligible. In its decision, the Supreme Court did not alter the fundamental test for patent eligibility, but rather applied it to Prometheus Labs' claims in a much more restrictive manner than had the Federal Circuit.

Prior to the *Mayo* decision, U.S. case law provided little guidance on two critical questions: (1) where is the line to be drawn between "natural" and non-natural phenomena, particularly in the realm of biology; and (2) what does it means to "impermissibly claim a natural phenomenon," as opposed to a patent-eligible application of that phenomenon? In *Mayo*, the Court adopts a very broad interpretation of the term "natural phenomenon," holding that the correlation between thiopurine drug metabolite concentration and optimal drug dosage "exists in principle apart from any human action [and] as a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes." Of course, the correlation does not exist naturally, but only as a consequence of introducing a non-naturally occurring, man-made molecule into the human body. In my view, such a correlation is not natural, and Prometheus Labs' claims should not implicate the patent-eligibility doctrine (which, incidentally, does not preclude the possibility that the claims are invalid on other statutory grounds, such as obviousness or lack of enablement). In contrast, the claims at issue in *LabCorp* and *Myriad*; i.e., the correlation between the concentration of vitamin B and homocysteine in the body, and naturally occurring variations in the *BRCA* genes, respectively, do appear to be based on natural phenomena (although in my view, those claims should nonetheless be deemed patent eligible).

In the decision below, the Federal Circuit had also found the correlation between drug metabolite concentration and optimal dosage to be a natural phenomenon but concluded that Prometheus Labs' claims were nonetheless patent eligible because they were limited to specific applications of the phenomenon. The Federal Circuit's analysis relied heavily on the *Bilski*[8] "machine-or-transformation" test and found that both the "determining" and "administering" steps were sufficiently tangible and transformative to render the claim patent eligible. Such an analysis would have maintained patent eligibility for drug method-of-treatment claims, as well as diagnostic claims that include a physically transformative step such as analyzing a patient sample for the presence of a molecular biomarker. The Federal Circuit viewed this physical analysis of a molecular sample as critical to patent eligibility. The *Myriad* claims, in contrast, were interpreted by the Federal Circuit to broadly encompass even the analysis of genetic sequence information, and I believe the lack of a step explicitly requiring the physical analysis of DNA molecules is what led the Federal Circuit to declare the Myriad method claims patent ineligible.

In the *Mayo* decision, the Supreme Court, on the other hand, found neither the "administering" nor the "determining" steps sufficient to render the claims patent eligible. The rationale provided by the Court is troubling. Justice Breyer dismissed the "administering" step as "simply refer[ing] to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs. That audience is a pre-existing audience; doctors used thiopurine drugs to treat patients suffering from autoimmune disorders long before anyone asserted these claims." It would seem, according to this logic, that the discovery of a new therapeutic use of a known drug should be considered patent ineligible, as there is already an audience of physicians using the drug to treat patients. I very much doubt that the Justices intended to foreclose the patenting of newly discovered uses of drugs, but a literal reading of the decision would seem to support that outcome.

Similarly, Justice Breyer declared the "determining" step to be "well-understood, routine and conventional" and hence insufficient to render the claims patent eligible. But again, think of the implications if this rationale were to be extended to method-of-treatment claims. In general, the administration of a known drug to a patient is "well understood, routine and conventional." But until now, it has been generally understood and accepted that a new, nonobvious, and useful method of employing a known drug to treat a disease can be patented. *Mayo* does not explain how one would distinguish between "well understood and routine" administration of a known drug in the context of a method-of-treatment claim on the one hand, and administration of the drug as it appears in the context of Prometheus Labs' claims.

[8] *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008).

In spite of the problematic language in *Mayo*, however, I predict that lower courts will be able to spin the decision in a way that preserves the patent eligibility of methods-of-treatment claims and most other biotechnology inventions that have traditionally been considered patentable. Significantly, at one point, the Court in *Mayo* observes that "[the patent claims in a] typical patent on a new drug or a new way of using an existing drug [include steps that] confine their reach to particular applications of [natural] laws," unlike the Prometheus Labs' claims, wherein the recited steps "add nothing of significance to the natural laws themselves." I think the drug industry, and the courts, will latch onto this dictum as evidence that the Supreme Court could not have intended *Mayo* to render conventional drug method claims patent ineligible.

In attempting to distinguish the 1981 *Diamond v. Diehr*[9] decision, in which the Supreme Court held a claim to be patent eligible even though it was based on a mathematical formula, *Mayo* explains that the *Diehr* claims included steps that "apparently added to the formula something that in terms of patent law's objectives had significance, [thereby transforming] the process into an inventive application of the formula." The steps recited in the *Diehr* claims, which included "installing rubber in a press, closing the mold [and] constantly determining the temperature of the mold," all seem quite routine and conventional. If the Federal Circuit is ever faced with the question of whether a method-of-treatment claim is patent eligible under *Mayo*, it can cite to this passage, conclude that the method-of-treatment claim at issue in the case includes a step that has "significance in terms of patent laws objectives," and declare the claim patent eligible. I do not believe that the Supreme Court would intervene to upset such an interpretation of *Mayo*.

Patent protection will in all likelihood remain available, at least in some form, for most innovation that occurs in biotechnology. *Mayo* has, however, injected greater uncertainty into the process and could substantially limit the availability of patents in some important areas, particular diagnostics and personalized medicine. Biotechnology will survive, but I suspect it would have been better if the Supreme Court had simply let the Federal Circuit's *Prometheus* decision stand.

The U.S. Patent and Trademark Office wasted no time in issuing preliminary guidance to the Patent Examining Corps on the impact of *Mayo* on subject matter eligibility under 35 U.S.C. §101, putting out a Memorandum dated March 21, 2012. *Biotechnology Law Report* has reproduced this Memorandum later in this issue, so our readers can see the PTO's own preliminary understanding of *Mayo*'s impact. Clearly, the issue of whether a claim recites patent-eligible subject matter will continue to surface in various guises. The impact of the decision on the patentability of isolated DNA, and natural products in general, will take center stage when the Federal Circuit takes up *Myriad* again in light of *Mayo.* Watch future issues of *Biotechnology Law Report* for reports of such developments and pertinent commentary from various perspectives.

[9]*Diamond v. Diehr*, 450 U.S. 175 (1981).

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Editorial

In *Myriad* the Supreme Court Has, Once Again, Increased the Uncertainty of U.S. Patent Law

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ON JUNE 13, the U.S. Supreme Court issued a unanimous decision in *Association for Molecular Pathology v. Myriad Genetics* (*Myriad)* that essentially upheld the patent eligibility of claims reciting cDNA molecules encoding BRCA proteins, but struck down as patent ineligible claims encompassing isolated fragments of BRCA-encoding genomic DNA. Unfortunately, as a consequence of the manner in which the case was decided, *Myriad* will in all likelihood only serve to increase the ambiguity and uncertainty plaguing the U.S. patent system. In that sense, the decision is entirely consistent with other recent patent decisions emanating from the Supreme Court—a few cases in point are *KSR*,[1] *Bilski*,[2] and *Festo*.[3]

Prior to *Myriad*, the understanding within the patent community with respect to biomolecules of natural origin was essentially that the threshold to patent eligibility could be crossed by a non-trivial act of human intervention. It was generally acknowledged that a naturally occurring biomolecule as it exists in its native state, such as genomic DNA as it normally resides in the human genome, is ineligible for patent protection, regardless of its utility or the ingenuity and effort required to discover it. But an act of human intervention that results in a product distinguishable from anything that occurs in nature was believed to be sufficient to enter into the realm of patent eligibility.

In particular, the isolation of a naturally occurring biomolecule from its native source was thought to render the isolated biomolecule a product "made by man" (to use the oft-cited language of the Supreme Court's 1980 decision in *Diamond v. Chakrabarty*[4]) and hence potentially patentable if the other requirements of patentability could be satisfied. Importantly, the criterion established for the threshold inquiry of patent eligibility; *i.e*., isolation from its native environment, was relatively clear-cut. Of course, this bright line test was never thought to render all isolated biomolecules patentable. The ultimate question of patentability (as opposed to patent eligibility) has always hinged on the utility and nonobviousness of the isolated compound, relatively objective inquiries that reflect the public policy concerns underpinning the patent system.

Myriad has changed the playing field, replacing a relatively clear line of demarcation between patent-eligible and patent-ineligible biomolecules with a more amorphous test that appears to incorporate considerations traditionally associated with other, more well-established requirements of patentability, such as novelty and nonobviousness. Clearly, the mere isolation of a naturally occurring biomolecule is no longer sufficient to confer patent eligibility on the isolated product, regardless of how useful, nonobvious, or inventive the isolated product is relative to the prior art. What is less clear is the patent eligibility status of a synthetic molecule that shares a common, or highly similar, structure with a naturally occurring biomolecule. This article explores some of the ambiguities created by the *Myriad* decision and considers some of the practical implications for patenting in the life sciences arena.

BIOMOLECULES ISOLATED FROM A NATURAL SOURCE

Decisions of the lower courts dating back more than 100 years have specifically upheld the validity of

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[1]*KSR Intern. v. Teleflex*, 550 U.S. 398 (2007)(striking down the Federal Circuit's attempt to impose objectivity on the obviousness analysis via the teaching–suggestion–motivation test).
[2]*Bilski v. Kappos*, 130 S. Ct. 3218 (2010)(striking down the Federal Circuit's attempt to establish the machine-or-transformation test as the sole criterion for patent eligibility of method claims).
[3]*Festo Corp. v Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002)(striking down the Federal Circuit's attempt to create a bright line rule for the application of prosecution history estoppel).
[4]*Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

claims directed toward biological molecules isolated from a natural source, most notably Judge Hand's influential decision in *Parke-Davis v. H.K. Mulford* upholding the validity of a product claim reciting human epinephrine (Adrenalin) purified from cadavers.[5] Judge Hand emphasized that although the compound might be chemically identical to the epinephrine that occurs naturally in the human body, its purification resulted in a pharmaceutical product with important therapeutic benefits that could not be replicated using unpurified epinephrine as it exists in its native state. More recently, guidelines issued by the U.S. Patent and Trademark Office concluded that isolated and purified naturally occurring DNA is patent eligible because the isolation and purification constitute sufficient human intervention to distinguish it from patent ineligible DNA as it exists naturally in the human body.[6]

It seems clear that under *Myriad*, the isolation of a natural product from a biological source is no longer to be construed as sufficient, in and of itself, to render the isolated product patent eligible, absent some further modification of the product. Although the case specifically focused on human genetic material, there is nothing in the decision to suggest that its effect should be limited to humans, nor to DNA. Under Justice Thomas' interpretation of 35 USC 101, only "new…compositions of matter" are patent eligible, and clearly in his view (and the view of the Court's), mere isolation is not enough to render a natural product "new." Thus, patent claims directed to other isolated natural products, such as proteins from plants or antibiotics from microbes, are apparently invalid absent some further human intervention that goes beyond merely isolating the product from its native source. Moving forward, those seeking protection for new and useful biomolecules derived from a natural source will need to pursue patent claims reciting additional limitations beyond mere isolation, perhaps by combining the biomolecule with some other composition of matter, or by significantly altering the chemical structure of the biomolecule.

SYNTHETIC VERSIONS OF NATURALLY OCCURRING BIOMOLECULES

It is important to distinguish between a biomolecule that has been produced naturally in a biological organism and then purified from its native source, on the one hand, and synthetic molecules that happen to share the same, or similar, chemical structure with a naturally occurring molecule. Relegating these synthetic molecules to the status of patent ineligible along with their naturally occurring counterparts would have a much more serious impact on biotechnology and pharmaceutical science than would be the case if only the naturally produced biomolecules were declared patent ineligible. This is particularly the case with respect to DNA. The power of DNA-based technology resides primarily in amenability of DNA to exponential amplification, using any of a variety of *in vitro* processes such as PCR, or in vivo processes that occur in recombinant host cells. These amplification processes are virtually ubiquitous in any practical exploitation of genetic sequence information, including diagnostic testing or recombinant protein expression, and are inherently based on the production of synthetic copies of the DNA of interest. As a practical matter, most biotechnology companies, including Myriad, have little need for patent protection of DNA molecules purified directly from a native source, so long as they are able to patent synthetic DNA molecules sharing the genetic sequence of a naturally occurring cognate.

Although I believe *Myriad* will most likely be interpreted in a manner rendering both native origin and synthetic versions of DNA (and more generally biomolecules) patent ineligible, the decision is not altogether unambiguous on this point. The Court never addresses the distinction between native origin and synthetic DNA, and I suspect that the Justices did not fully appreciate its significance. The language of *Myriad* suggests that the Justices assumed that the invalidated claims encompassed native source DNA molecules that had been extracted from naturally occurring genomic DNA simply by severing chemical bonds that attach the isolated fragment to the rest of the genomic DNA, in a manner analogous to plucking a leaf from a tree or removing a kidney from a patient. The decision does not expressly address the patent eligibility of a claim limited to synthetic DNA molecules that correspond in sequence to a naturally occurring genomic DNA sequence.

Bear in mind that a patent claim is patent ineligible if it extends to any patent-ineligible subject matter, even if some (or most) of the subject matter falling within the scope of the claim is patent eligible. The Court specifically found that at least some of Myriad's invalidated claims encompass both eligible and ineligible subject matter. For example, patent-eligible Claim 2 of U.S. Patent 5,747,282 (limited to cDNA) depends from patent-ineligible Claim 1 of the same patent, from which it can be inferred that Claim 1 encompasses the patent-eligible cDNA molecules recited in Claim 2. The Supreme Court held Claim 1 to be patent ineligible because it encompasses native origin genomic DNA "cleaved" from the human genome, but never specifically addressed the patent eligibility of synthetic DNA molecules other than cDNA. I think one could argue that *Myriad* does not

[5] *Parke-Davis v. H.K. Mulford*, 189 F. 95 (S.D.N.Y. 1911).
[6] Utility Examination Guidelines, 66 Fed. Reg. 1092 (January 5, 2001).

necessarily preclude the patent eligibility of a claim limited to synthetic DNA molecules, even if those molecules share the sequence of naturally occurring genomic DNA.

In explaining its conclusion that cDNA is patent eligible, the Court emphasized that the claimed cDNA was "synthetically created," while the invalidated claims encompassed "naturally occurring DNA isolated from the rest of the human genome." The Court pointed out that cDNA is structurally distinct from mRNA, but as I explained in an *amicus* brief I submitted to the Federal Circuit the second time it heard *Myriad*, synthetic DNA produced using processes such as PCR, or produced in recombinant organisms, is generally structurally distinct from the corresponding native genomic DNA from which it was derived.[7] For example, the synthetic DNA generally lacks the epigenetic modifications, such as methylation, typically found in human genomic DNA. Synthetically amplified genomic DNA is no less synthetic than cDNA, and the extent of structural divergence between cDNA and the mRNA from which it was derived would appear to be comparable to the structural difference between synthetic and native genomic DNA. The Court did seem to find it significant that isolated genomic DNA retains the genetic information embodied in the DNA residing in the human genome, but by the same token, cDNA retains the genetic information of the mRNA from which it was derived.

Thus, *Myriad* might plausibly be interpreted as allowing the patent eligibility of synthetic DNA corresponding in sequence to naturally occurring DNA, or more generally, the patent eligibility of synthetic molecules sharing the structure of a naturally occurring cognate. In assessing patent eligibility of a synthetic biomolecule, a court might need to consider the extent and significance of any structural differences between synthetic and native-origin molecules, the functional consequences (if any) of the structural distinction, and the level of specificity at which the structural difference can be defined, and perhaps specifically identified, by the patentee in the specification and/or claims.

For example, the cDNA claims upheld by the Court provided the specific sequence of the claimed DNA molecules. In contrast, the isolated DNA claims that were struck down defined the DNA solely in terms of the functional ability to encode BRCA protein. The Court expressly acknowledged that the isolated DNA molecules recited in the invalidated claims are structurally different from DNA that occurs naturally in the genome secondary to the cleavage of covalent bonds during excision of the claimed molecule from the genome, but points out that the invalidated claims "are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA." This might be interpreted as suggesting that claims reciting synthetic versions of genomic DNA could be patent eligible if there are structural differences between the synthetic and native source DNA molecules, and those structural differences are called out in the claim.

For example, what if Myriad's patent had a claim reciting something along the lines of "a synthetic, non-naturally occurring DNA coding for a BRCA1 polypeptide, wherein the synthetic DNA lacks post-translational epigenetic modifications found in the native human *BRCA* gene"? Like the cDNA claims upheld by the Court, the claim is limited to synthetic molecules that differ structurally from anything that occurs naturally, and the difference in structure is incorporated in the claim. Unlike the cDNA claims, however, the specific structural features are not recited in this hypothetical claim, and this lack of specificity could cause patent eligibility concerns, as well as other issues of patentability, such as indefiniteness under 35 USC 112(b).

In fact, this claim format is very similar to one used by Amgen years ago to claim recombinant erythropoietin in a manner that distinguishes over a prior art disclosure of native erythropoietin purified from human urine. Claim 1 of Amgen's U.S. Patent Number 5,547,933, for example, recites a "non-naturally occurring erythropoietin glycoprotein product having the *in vivo* biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells and having glycosylation which differs from that of human urinary erythropoietin." This claim was ultimately invalidated by the Federal Circuit for indefiniteness in *Amgen v. Hoechst Marion Roussel*, due in large part to the heterogeneity associated with glycosylation patterns in human urinary erythropoietin.[8] Still, the Federal Circuit's decision was specific to the facts as they were developed in that particular case, and does not necessarily preclude the idea of achieving patent eligibility by claiming synthetic biomolecules in a manner that recites structural distinctions, particularly if the structural differences can be recited to a higher degree of specificity.

HOW MUCH DIFFERENCE IN STRUCTURE IS REQUIRED FOR PATENT ELIGIBILITY?

Myriad is also ambiguous with respect to the degree of structural difference between a claimed

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[7] *The Association for Molecular Pathology v. U.S. Patent and Trademark Office*, Federal Circuit Court of Appeals Docket No. 2010-1406, Brief of *Amicus Curiae* Law Professor Christopher M. Holman in Support of Neither Party, 2012 WL 2884112 (June 13, 2012).

[8] *Amgen v. Hoechst Marion Roussel*, 314 F.3d 1313 (Fed. Cir. 2003).

biomolecule and its native counterpart necessary to confer patent eligibility on the claimed biomolecule. The Justices appeared to find the synthetic origin of cDNA relevant to the patent eligibility inquiry, but the Court also emphasized the structural difference between cDNA and the corresponding genomic DNA. As discussed above, under one plausible interpretation of *Myriad*, the synthetic origin of the molecule is sufficient in and of itself to achieve patent eligibility. It seems more likely, however, that the structural difference between cDNA and native DNA was critical to the Court's conclusion that cDNA is patent eligible, suggesting that structural differences are a key to patent eligibility.

In this regard, *Myriad* suggests that some structural differences are simply too insubstantial to establish a basis for patent eligibility. The Court specifically points out that "Myriad's claims [are not] saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule." Unfortunately, the Court does not provide a very satisfactory explanation of why the structural differences between cDNA and mRNA are sufficient to establish patent eligibility, while the structural differences between "isolated" and naturally occurring genomic DNA are not. The Court points out that cDNA lacks the introns present in most human genomic genes, but that is a false comparison—cDNA is not derived from genomic DNA, but rather from mRNA, which is just as much a naturally occurring molecule as genomic DNA and which lacks the introns present in genomic DNA.

The structural differences between cDNA and mRNA are much less pronounced than the differences between cDNA and genomic DNA. The extent of the difference is that the nucleotide subunits of cDNA are missing an oxygen atom compared with mRNA, and in cDNA, uracil is replaced by thymine (uracil and thymine are almost identical, differing by a single methyl group). It is true that these relatively minor structural differences do have significant functional consequences, but the same can be said with respect to the loss of epigenetic modification that generally occurs in the process of making synthetic copies of native human genomic DNA.

The Court might have provided more guidance with respect to the test for patent eligibility if it had adopted the approach suggested by Justice Scalia in his one-paragraph concurrence. Scalia began by disassociating himself from those portions of Justice Thomas' opinion that went into the "fine details of molecular biology," explaining that he was "unable to affirm those details to [his] own knowledge or even [his] own belief." To his credit, Scalia at least has the self-awareness and candor to acknowledge that he is in no position to expound on the intricacies of molecular biology. He did, however, agree with his colleagues that Myriad's claimed isolated DNA molecules are patent ineligible because, to his understanding, they are "identical to that portion of the DNA in its natural state," whereas the claimed cDNA "is a synthetic creation not normally present in nature."

While avoiding entanglement in the intricacies of the technology, Scalia's approach would have the not-insubstantial merit of at least providing the basis for something approaching a bright line rule for the patent eligibility of natural products. To wit, the mere isolation of a natural product is insufficient to confer patent eligibility on the isolated product absent some structural modification to the molecule that renders it a non-identical, synthetic creation not normally present in nature. This is not to say that I agree with his conclusion. In my view, isolation of a natural product should be enough to render the isolated product patent eligible. But at least Scalia's distinction between "identical" and "not normally present in nature" would provide more guidance going forward than the Court's more ambiguous statement of the test for patent eligibility.

IMPLICATIONS FOR BIOTECHNOLOGY

The impact of *Myriad* on biotechnology will to a large extent depend on how the decision is interpreted and applied by the lower courts. As discussed above, the decision could be construed in a manner that would maintain patent eligibility for synthetic versions of naturally occurring biomolecules, at least if some minimal degree of structural variation exists between synthetic and native forms of the molecule. This would still leave biomolecules isolated from a native source ineligible for patent protection, but we can hope that the developers of such products will be able to secure adequate patent protection using alternate claiming strategies, such claims directed toward methods of using or producing the biomolecules, or product claims reciting additional limitations beyond mere isolation, such as a pharmaceutical composition comprising the biomolecule, or a composition comprising the biomolecules in combination with some other obligatory constituent.

On the other hand, if the decision is interpreted in a manner that extends to synthetic versions of biomolecules, including biomolecules with some structural variation from their native counterpart, the impact on biotechnology could be more serious. For example, what would be the patent-eligibility status of a DNA-based gene therapy vector based on a naturally occurring DNA sequence? Or what about monoclonal antibody-based drugs, some of which represent the most financially and medically significant products of biotechnology? Therapeutic monoclonal antibodies are designed to structurally resemble human antibodies, but could that structural similarity render them

patent ineligible in view of naturally occurring human monoclonal antibodies? With the upsurge in reports of antibiotic resistant "superbugs," there is a critical need for novel antibiotics, but could *Myriad* cast a shadow over the prospects of patent protection for antibiotics isolated from naturally occurring microorganisms?

Unfortunately, *Myriad*, in conjunction with other recent decisions such as *Mayo v. Prometheus*,[9] has increased the uncertainty regarding the availability of effective patent protection in important areas of biotechnology and pharmaceutical research, potentially to the detriment of future investment in research and development. Since the Supreme Court has spoken, it might be up to Congress to remedy the situation by amending the patent statute in a manner that overrules *Myriad*, at least with respect to synthetic molecules that share structural similarity, or even identity, with a naturally occurring biomolecule. This would shift the focus in determining the patentability of these molecules to the questions of novelty, nonobviousness, and utility, allowing patent protection in cases where that protection is both justified and entirely consistent with sound public policy.

[9]*Mayo v. Prometheus*, 132 S. Ct. 1289 (2012).