

U.S. Patent Law is like a Box of  
Chocolates:  
You Never Know What You Are Going to  
Get

(Subtitled: Chaos in the courts, Congress and the PTO)

Paul S. Tully, Ph.D.

Kevin E. Noonan, Ph.D.

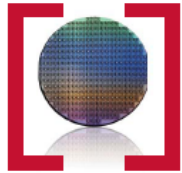
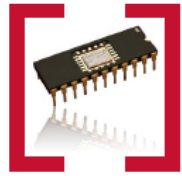


McDonnell Boehnen Hulbert & Berghoff LLP

# Who We Are: McDonnell Boehnen Hulbert & Berghoff

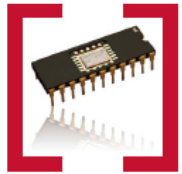


- Opened doors October 7, 1996 with 8 lawyers
- 85 lawyers currently, projected to top 100 lawyers by 2011
- Full service firm: prosecution, litigation, strategic counseling, licensing
- Headquartered in Chicago, we also have an office in the Seattle area.





# Our People



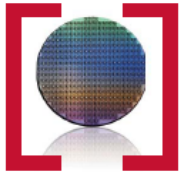
- Currently, MBHB has 85 attorneys and 12 technical professionals.



- More than half hold advanced technical degrees.

- 21 hold doctorates.

- All attorneys and technical professional are admitted to practice before the U.S. Patent and Trademark Office.



# Paul S. Tully, Ph.D.

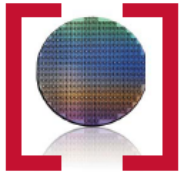
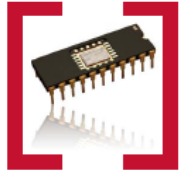
- Education
  - J.D., The John Marshall Law School, *cum laude*, 1999
  - Ph.D., M.S., Organic Chemistry, Northwestern University, 1992
  - B.S., Organic Chemistry, Eastern Illinois University, 1989
- Bar admissions
  - Supreme Court of Illinois
  - Court of Appeals for the Federal Circuit
  - U.S. Court of Appeals for the Seventh Circuit
  - U.S. Patent and Trademark Office
- Honors & awards
  - CALI Excellence For The Future Award - Property
  - The American Society of Writers on Legal Subjects Scribes Award
  - Corpus Juris Secundum Award – Property
  - Northwestern Law Review\Illinois Super Lawyers Rising Star
  - Past Vice-Chair, IPO Counterfeiting and Piracy 2007-2008





# Kevin E. Noonan, Ph.D.

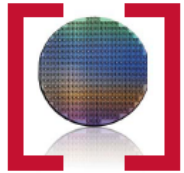
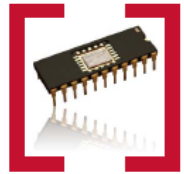
- Education
  - J.D., The John Marshall Law School, *cum laude*
  - Postdoctoral Fellowship - National Cancer Institute
  - Ph.D., Princeton University, Molecular Biology
  - B.S., State University of New York
- Bar admissions
  - Illinois
  - Massachusetts
  - Court of Appeals for the Federal Circuit
  - U.S. Patent and Trademark Office
- Professional leadership
  - Adjunct Professor:
  - DePaul University College of Law
  - John Marshall Law School
  - Founding author, *Patent Docs* weblog



# Our clients



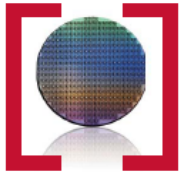
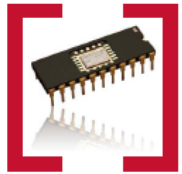
- *Fortune* 500 companies
- Start-ups
- Universities
- Individual inventors, and
- Entrepreneurs and investment bankers



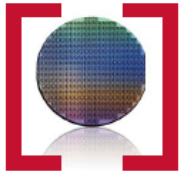
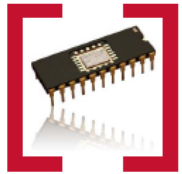
# Technology areas




- Our attorneys have practical industry experience in fields including:
  - biotechnology
  - chemistry
  - pharmaceuticals
  - diagnostics
  - electrical engineering
  - telecommunications
  - mechanical and material science
- As well as advanced degrees in the relevant fields



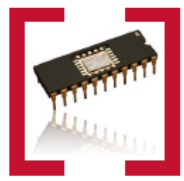

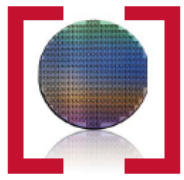
# Our Experience




- Our practice areas encompass all aspects of intellectual property law – including:
  - litigation,
  - prosecution
  - opinions
  - strategic counseling
- Our attorneys practice in the areas of:
  - Patent procurement and enforcement
  - Trademark procurement and enforcement
  - Unfair competition/antitrust issues (related to patents)
  - US District Court, Federal Circuit and ITC actions

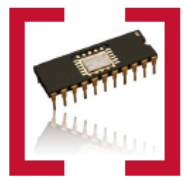



# The Box of Chocolates: Currently a time great change in US patent law

- 
- US patent law underwent last major revision in 1952
  - Several small tweaks in the interim - 1984 (Hatch-Waxman); 1988 (271(f)); 1995 (GATT/TRIPs); 2000 (patent publication/AIPA)
  - Long period in which patent law was permitted to develop unhindered by interference from legislature
- 
- 



# US patent system a victim of its own success

- 
- We live in a technological age
  - Creation of CAFC brought procedural and doctrinal stability to patent law
  - CAFC decisions aimed at bringing business certainty
    - Limitations on Doctrine of Equivalents
    - Written description an enhanced requirement
    - Claim construction by the court rather than a lay jury
    - De novo review by the CAFC to keep district courts in line



# US patent system a victim of its own success

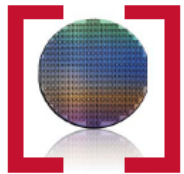
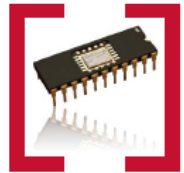
- But this created perceived winners and losers

- Winners

- Pharma
- Biotech
- Universities
- Small inventors

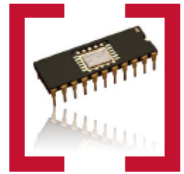
- Losers

- Information technology companies
- Software developers
- Large corporations in general

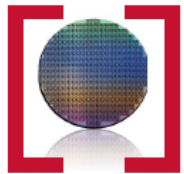





# US patent system a victim of its own success

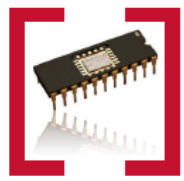


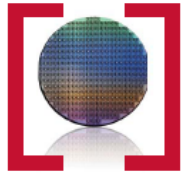
- Pharma/biotech opposed
  - Difference in industries
  - Pharma/biotech investor/capital intensive
  - IT can be a bright teenager with a laptop
  - Also timelines: pharma/biotech patents protect throughout the patent term; IT patents become obsolete much faster
- So far, the opposition has been just strong enough





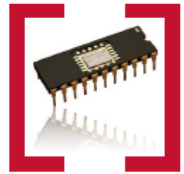
# US patent system a victim of its own success

- 
- “Patent reform” on three fronts
    - Administrative: U.S. Patent and Trademark Office has promulgated rules limiting how many continuation applications can be filed and limiting the number of claims per application, among others
    - A totally bureaucratic response to backlog
    - New PTO Director withdrew rules and abandoned appeal
    - BUT asking Congress for “substantive rulemaking authority”

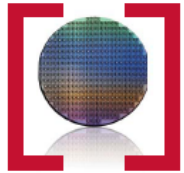




# US Patent system a victim of its own success



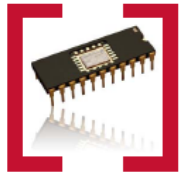
- “Patent reform” on three fronts
  - Judicial: several cases from U.S. Supreme Court and CAFC changed the law
    - *KSR v. Teleflex*: obviousness
    - *eBay v. MercExchange*: injunctions
    - *Genentech v. Medimmune*: capacity for licensee to sue patentee because patent invalid





# *KSR Procedural History*

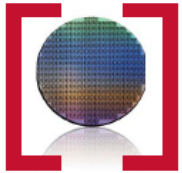
- District court – TSM test was met, claims invalid; Graham v. John Deere factors alive and well; “obvious to try,” not so much



- Appellate court – TSM test was not met; reversed District Court



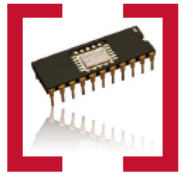
- Supreme Court – TSM is demoted



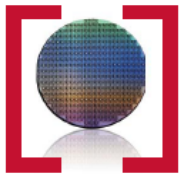


# *KSR v. Teleflex*

■ Supreme Court, in dicta, elevates relevance of instances when something that is "obvious to try" is also obvious:

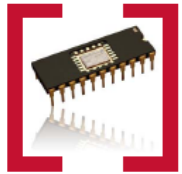


"When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."





# Chemical Obviousness after *KSR*

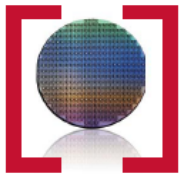


- *KSR* lowered the standard for finding an invention obvious



- Increased the scope of prior art

- Introduced concept of “common sense” and “ordinary creativity”

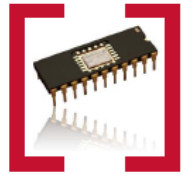


- Focused inquiry on “obvious to try”



# Quotations from *KSR*

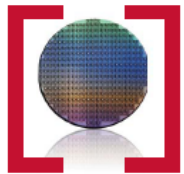
- “Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.”



- “One of the ways in which a patent’s subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent’s claims.”



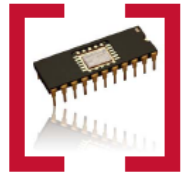
- “[T]ake account of the inferences and creative steps that a person of ordinary skill in the art would employ.” .



- “A person of ordinary skill is also a person of ordinary creativity, not an automaton.”



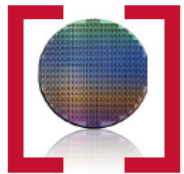
# Quotations from *KSR*



■ “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield **predictable results** ...”



■ “If a person of ordinary skill can implement a **predictable variation**, §103 likely bars its patentability.”

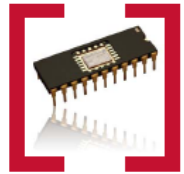


■ “... a court must ask whether the improvement is more than the **predictable** use of prior art elements according to their established functions.”



# Chemical Obviousness after

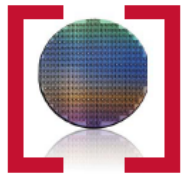
▪ *Bayer Schering v. Barr* **KSR** an example of this trend



▪ Claims to a new formulation of an old contraceptive, having additional diuretic properties (Yasmin®)



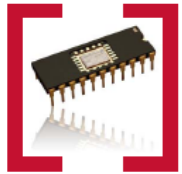
▪ Evidence that active ingredient acid-labile, but that formulation orally available only when *not* enterically coated



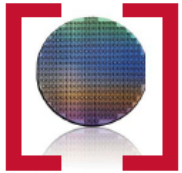
▪ Claims obvious, based on analysis that there were two choices (to coat or not to coat), and it would have been within ordinary skill to try both



# Post-KSR Considerations

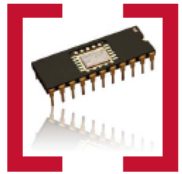


- If possible, show that  $1+1=3$  early and often
- Focus on (lack of) predictability rather than explicit teachings or misapplication of TSM
- Teaching away from combination still important
- Likely increase in patent challenges under §103? – The jury is still out on this one

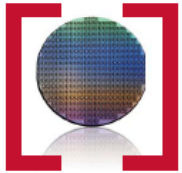




# Post-KSR Considerations

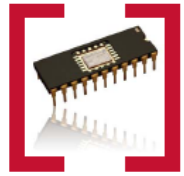


- *KSR* has not had a major negative effect on the ability of applicants to obtain patents – so far.
  - It easier for examiners to make rejections based on an “apparent reason to combine” known elements.
  - TSM still alive and required to be applied by examiners, per MPEP § 2143.

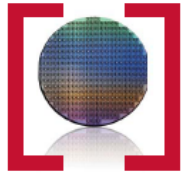




# US Patent system a victim of its own success



- “Patent reform” on three fronts
  - Legislative: being considered by Senate, not yet in House of Representatives
    - Some major changes
      - *First to file (but maintaining grace period)*
      - *Post-grant opposition*
      - *Statutory limitations on patent damages*
      - *Weakening of best mode requirement*

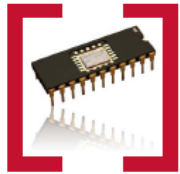




# Legislation in 111<sup>th</sup> Congress

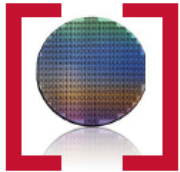
## ▪ Patent Reform Legislation:

- S. 515 – Sen. Patrick Leahy (D-VT)
- H.R. 1260 – Rep. John Conyers (D-MI)
- S. 610 – Sen. Jon Kyl (R-AZ)



## ▪ Follow-on Biologics Legislation:

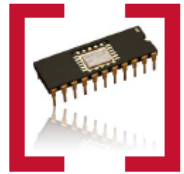
- H.R. 1427 – Rep. Henry Waxman (D-CA)
- H.R. 1548 – Rep. Anna Eshoo (D-CA)
- S. 726 – Sen. Charles Schumer (D-NY)





# Patent Reform Legislation

## Key aspects of S. 515:

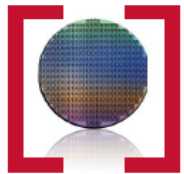


- Replaces first-to-invent with first-inventor-to-file (with no requirement that Europe and Japan implement one-year grace period),



- Would create post-grant review period (12 months following issuance) and expanded *inter partes* reexamination procedure,

- Provides gatekeeper approach for determining damages,

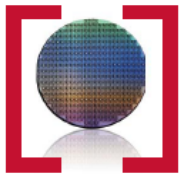
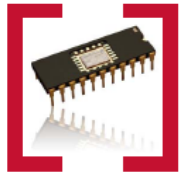


- No inequitable conduct provision, and
- No Applicant Quality Submissions (AQSs).



# Follow-on Biologics

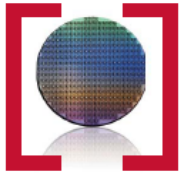
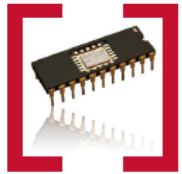
- All three bills would create a follow-on biologics regulatory pathway in the United States.
- Exclusivity provided to innovator drug companies:
  - Waxman bill (H.R. 1427) – up to 5.5 years
  - Eshoo bill (H.R. 1548) – up to 12 years
- Waxman bill – supported by generic drug companies and GPhA.
- Eshoo bill – supported by innovator drug companies and BIO.





# Follow-on Biologics

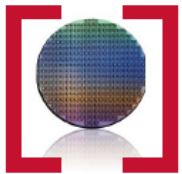
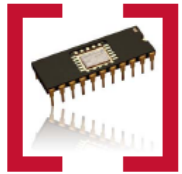
- Duke study estimates 12.9-16.2 year break-even point for biologics – Grabowksi, *Nature Reviews Drug Discovery* 7: 479-88 (2008).
- Teva study concludes that 7 year data exclusivity period would sufficiently balance incentives for innovators with market benefits of competition – Brill, "Proper Duration of Data Exclusivity for Generic Biologics: A Critique," November 2008.





# *In re Kubin*

- Affirmed Board's decision that gene claim obvious
- Determined that *KSR's* reliance on an "obvious to try" analysis overruled *Deuel*
- Turns the *Deuel* analysis on its head, by holding that the "routine" nature of the cloning methods is not the issue, since methods are not being claimed
- Eschews *Deuel's* principles of "structural obviousness"
- Appears at odds with statutory proscription against using methods to establish obviousness



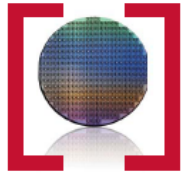
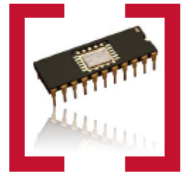


# Implications of *Kubin*

USPTO has directed examiners to follow it

## Decision

- Examination Guidelines for Determining Obviousness under 35 U.S.C. 103 in view of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526 (October 10, 2007)
- Guideline E. "Obvious to Try" – Choosing from a Finite Number of Identified, Predictable Solutions, with a Reasonable Expectation of Success
  - Example 3: *Ex parte Kubin*



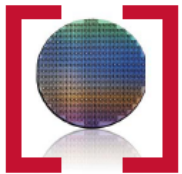
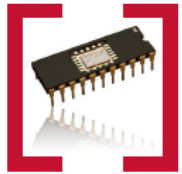


# Implications of *Kubin*

Post-*Kubin*, patentability of gene will likely hinge on:

## Decision

- Lack of motivation in the art to clone the gene (*i.e.*, the gene is unknown)
- *Caveat*: Even if protein was not known, known family members or motifs may be deemed sufficient to provide motivation
- Unusual difficulty in cloning the gene
- Lack of expectation of success
- Surprising results, *e.g.*, alternative splicing

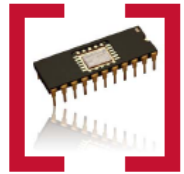




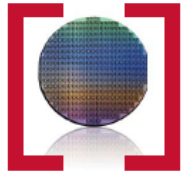
# Implications of *Kubin*

Court's rationale could have repercussions outside of gene patents:

## Decision



- Known screening assays make any compounds identified in the assays obvious?
- Known synthetic methods make all variants of a known compound obvious?
- Known methods of making antibodies make all antibodies specific for a known antigen obvious?

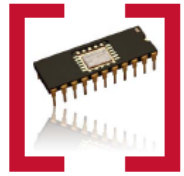


# The Current Threat



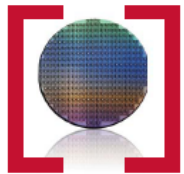
- *In re Bilski*

- The Bilski claims
- Federal Circuit decision *en banc*
- Dissenting views
- Supreme Court review



- *Labcorp v. Metabolite*

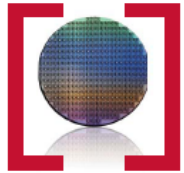
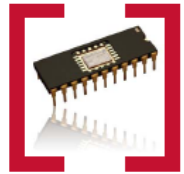
- The claims
- The Supreme Court argument
- The dissent from dismissal of cert





# *In re Bilski*: The New Rule

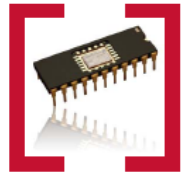
- New test: A process claim must:
  - Be tied to a particular machine or apparatus;  
or
  - Transform a particular article into a different state or thing
- Decision not limited to technology area or type of method claim; applies to all method claims



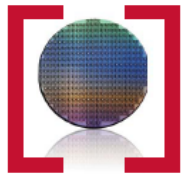


# *In re Bilski*: The New Rule

## First prong: Tied to a particular machine



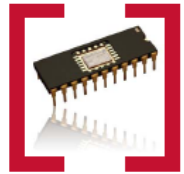
- A general-purpose computer insufficient
- Decision does not provide guidance as to "how much" the process must be tied to the machine or apparatus
- "We leave to future cases the elaboration of the precise contours of machine implementation, as well as the answers to particular questions, such as whether or when recitation of a computer suffices to tie a process claim to a particular machine."



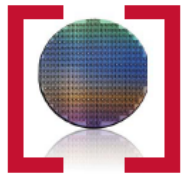


# *In re Bilski*: The New Rule

**Second prong: Transforms an article into a different state or thing**



- Chemical or physical transformations of physical objects or substances satisfy the test
- Transforming data into a particular visual depiction of a physical object – displaying data on a screen
- "Transformation and reduction of an article 'into a different state or thing' is **the** clue to the patentability of a process claim that does not include particular machines," *citing Diamond v. Diehr*

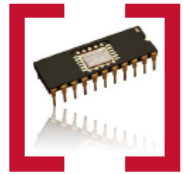




# *In re Bilski*: The New Rule

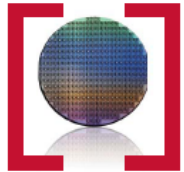
- **What does not satisfy the second prong:**

- Merely gathering data inputs for use in the process not enough
- Merely performing mathematical calculations on data not enough



- **What does not satisfy either prong:**

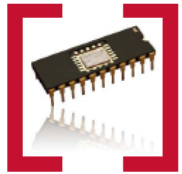
- Limiting use of an algorithm to a particular technology
- Insignificant post- or extra-solution activity





# *LabCorp:* Background

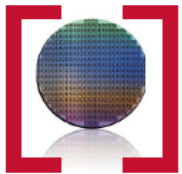
Claim 13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:



assaying a body fluid for an elevated level of total homocysteine; and



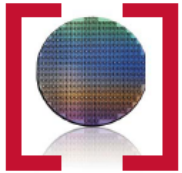
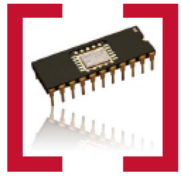
correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.





# *LabCorp*

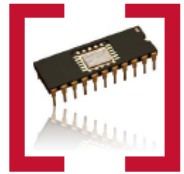
- District Court and CAFC hold claim not invalid and infringed
- Supreme Court grants certiorari based on argument that claims not patent eligible
- Court hears argument and dismisses petition
- Dissent from dismissal by three justices: Breyer, Souter and Stevens
- Justice Breyer writes the dissent



# Labcorp Dissent



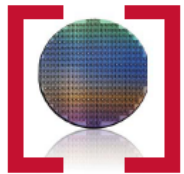
“As construed by the Federal Circuit, claim 13 provides those researchers with *control over doctors' efforts* to use that correlation to diagnose vitamin deficiencies in a patient. Does the law permit such protection or does claim 13, in the circumstances, amount to an invalid effort to patent a ‘phenomenon of nature’”?



“At most, respondents have simply *described the natural law* at issue in the abstract patent language of a ‘process.’ But they cannot avoid the fact that the process is no more than *an instruction to read some numbers in light of medical knowledge.*”



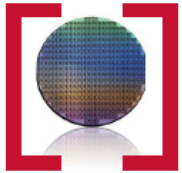
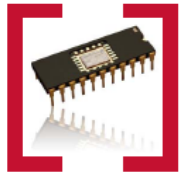
“[H]ere, aside from *the unpatented test*, they embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is *an unpatentable ‘natural phenomenon,’* and I can find nothing in claim 13 that adds anything more of significance.





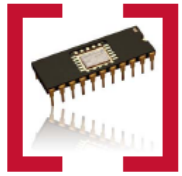
# *LabCorp*: Justice Breyer's Dissent

- Justice Breyer misses a few points of well-established patent law:
- Whether a claim recites patent-eligible subject matter does not depend on whether the claim is itself patentable
- Applications of "phenomena of nature" are patentable; the phenomenon itself is not
- Perhaps in conflict with 35 U.S.C. § 100(b)





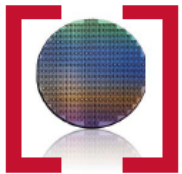
# Effects of *LabCorp/Bilski* in the USPTO and District Courts



- Several District Court decisions invalidating diagnostic method claims in view of *LabCorp* dissent; two appealed to CAFC



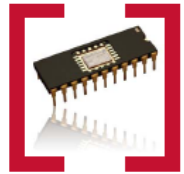
- Patent Office using *Bilski* liberally (>20 decisions) for rejecting method claims generally, not limited to business methods (*Bilski* not so limited)



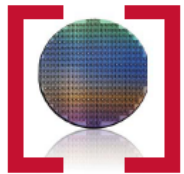
- Not yet extended to diagnostic method claims



# *Labcorp* Dissent – Some Context



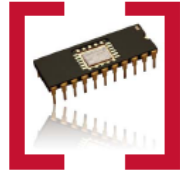

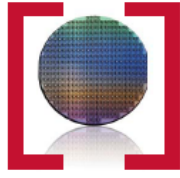
- General problem of “determine and infer” claims (Prof. Kevin Emerson Collins):
  - Characterized by one or more “determining” steps that involve assays, etc. = transformative
  - Include “mental step” of reaching a conclusion or arriving at an inference based on outcome of determining steps
  - Claim preamble directs method to activity (e.g., diagnosing) based on inference



# Consequences of *Bilski* Decision



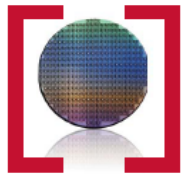
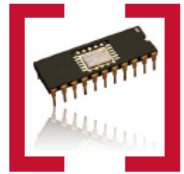
- *Classen Immunotherapeutics v. Biogen Idec*

- 
- Claims a method for determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder (CIMD)
- 
- Recites steps of immunizing mammals according to an immunization schedule, and comparing the incidence, prevalence, frequency or severity of CIMD (or the level of a marker of such a disorder) between treatment group and control group
- 
- “Transformation” = immunize and “create” CIMD

# Consequences of *Bilski* Decision



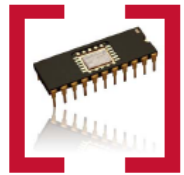
- *Prometheus Labs v. Mayo* (decided September 16, 2009)
  - Claims a method for optimizing treatment of an immune-mediated gastrointestinal disorder with 6-thioguanine
  - Recited steps of administering the drug to a patient and detecting 6-thioguanine or 6-methyl-mercaptopurine (metabolite) in blood
  - Recites inferring step of therapeutic efficacy when 6-thioguanine levels in red blood cells are between 230 pmol-400 pmol per  $8 \times 10^8$  red blood cells
  - Levels outside these ranges “indicates a need” to adjust administration amounts accordingly – but does not recite affirmative steps of adjusting



# Prometheus Labs v. Mayo



- Steps for administering a drug and determining metabolites can be transformative and satisfy *Bilski*

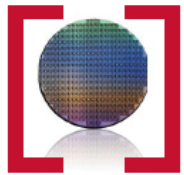


- Such steps can be “method of treatment” steps that are “always transformative”



- Involving “natural processes” not determinative, since “every transformation of physical matter . . . occurs as the result of natural processes”

- A process for chemical or physical transformation of a physical object or substance are “virtually self-evidently” patent-eligible subject matter

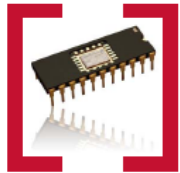


- Inclusion of a mental step does not negate patent-eligibility



# Consequences

## Diagnostic claims at risk

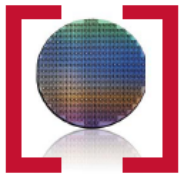


- (Almost) all diagnostic method claims will involve detecting a correlation between a biomarker and a biological condition (a disease, activity of biological function)



- Compositions of matter/kit claims may not be available due to prior disclosure by, inter alia, the Human Genome Project

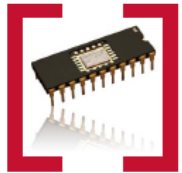
- "Mental Step" or "natural phenomenon"



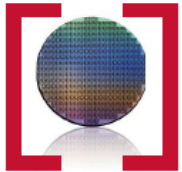


# Recommendations

Can limit claims to conform to the *Bilski* requirements:



- Tie the method to a machine or apparatus
- Require data or other information to be displayed
- Transmit/display data to third party
- Recite method of treatment step relating to diagnosis
  - But this raises *MuniAuction* issues

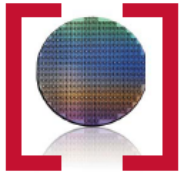
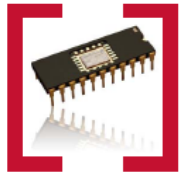




# Recommendations

## Other Suggestions:

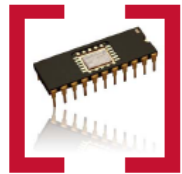
- Avoid mere data manipulation in claims
- Craft preamble to be directed to concrete result
- Include active steps embodying physical transformation of assayed biological material
- Direct method for determining treatment without including treatment step





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