BAKER DONELSON

INTELLECTUAL PROPERTY SYMPOSIUM

March 20-22, 2012
New Orleans, Louisiana



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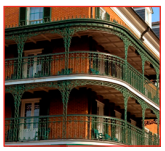

March 20 - 22, 2012
New Orleans

DETAILED AGENDA

Tuesday, March 20

Morning Session

8:00 a.m. - 8:30 a.m.	Registration and Breakfast
8:30 a.m. - 9:30 a.m.	**Intellectual Property 101** *Warner Delaune, Baker Donelson, Baton Rouge, Louisiana*
9:30 a.m. - 10:15 a.m.	**Dealing With Difficult Examiners: Getting to Allowance** *Richard Henderson, Ph.D., Baker Donelson, Washington, D.C.* *David L. Vanik, Ph.D, Baker Donelson, Washington, D.C.*
10:15 a.m. - 10:30 a.m.	**Search Issues Under the AIA** *Drew Lowery, Ph.D., Global Prior Art*
10:30 a.m. - 10:45 a.m.	Networking Break
10:45 a.m. - 11:45 a.m.	**Mergers & Acquisitions /Licensing Panel Discussion** *Moderator: David Rieveschl, Baker Donelson, New Orleans, Louisiana*
11:45 a.m. - 12:15 a.m.	**Hot Topics in Import/Export Law** *Hena Schommer, Baker Donelson, Washington, D.C.*
12:15 p.m.	Lunch

Afternoon Session

1:00 p.m. - 2:30 p.m.	**Tour of Mardi Gras World** *Enjoy King Cake, learn the history of Mardi Gras and tour the facilities while artists are constructing the world famous Mardi Gras parade floats!* Meet in the JW Marriott lobby at 1:00 p.m. to board the Mardi Gras World shuttle in the valet circle drive. Beverages and snacks are allowed on the shuttle.
2:30 p.m. - 5:30 p.m.	Free Time
6:00 p.m.	**Dinner at Arnaud's in the French Quarter** Meet in the JW Marriott lobby at 5:45 p.m. to walk with the group to Arnaud's. A map with walking directions is included in your welcome bag.

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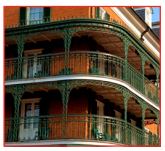

Wednesday, March 21

Morning Session

8:00 a.m. - 8:30 a.m.	Breakfast
8:30 a.m. - 9:00 a.m.	**The New Patent Law: The Good, The Bad & The Ugly** *W. Edward Ramage, Chairman, Intellectual Property Group, Baker Donelson, Nashville, Tennessee*
9:00 a.m. - 9:30 a.m.	**The Meaning of "Disclosed"** *Shazi Jiang, M.D., Baker Donelson, Washington, D.C.*
9:30 a.m. - 10:15 a.m.	**Test Driving New § 102: An Analysis of Priority Contests** *Bryan Jones, Baker Donelson, Washington, D.C.*
10:15 a.m. - 10:30 a.m.	Networking Break
10:30 a.m. - 11:00 a.m.	**Can You Cure Inequitable Conduct?** *Chris Holly, Ph.D., Baker Donelson, Washington, D.C.*
11:00 a.m. - 11:45 a.m.	**Anatomy 2011: Dissecting 12 months of CAFC Jurisprudence** *Samuel Miller, Baker Donelson, Nashville, Tennessee*
12:00 noon	Lunch

Afternoon Session

1:00 p.m. - 4:30 p.m.	**Jean Lafitte Swamp Tour** *Experience a real-life adventure from the comfort of swamp boats. Tour the bayous and view moss draped cypress trees, fascinating plant life and the creatures who make their homes here. A Cajun guide will share the legends and lore of Louisiana's wilderness!* Meet in the JW Mariott lobby at 12:45 p.m. to board the bus in the valet circle drive. Dress in casual, comfortable attire.
5:00 p.m.	Free Time & Dinner on Own

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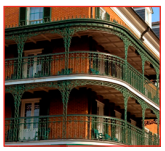

Thursday, March 22

Morning Session

8:30 a.m. - 9:00 a.m.	Breakfast at the JW Marriott Hotel
9:00 a.m. - 12:00 p.m.	**Walking Tour of New Orleans Cemetery & French Quarter** *Stroll through the past and present of New Orleans at the St. Louis Cemetery #1.Then explore the storied streets of the French Quarter, from the dynamic Mississippi River to the serene courtyards, ending at the world famous Cafe Du Monde restaurant.* Following breakfast at the JW Marriott, the group will walk to the St.Louis Cemetery #1. A map with walking directions is included in your welcome bag. Dress in casual attire and comfortable walking shoes.
12:00 p.m. - 2:00 p.m.	Free Time & Lunch on Own

Afternoon Session

2:45 p.m. - 3:15 p.m.	**UPDATE: Hot Topics in Trademark Law** *Micheline Johnson, Baker Donelson, Chattanooga, Tennessee*
3:15 p.m. - 4:15 p.m.	**Public Policy & Patents** *Laine Glisson Oliver, Baker Donelson, Washington, D.C.* *James C. Sandberg, Baker Donelson, Washington, D.C.*
4:15 p.m. - 4:30 p.m.	Networking Break
4:30 p.m. - 5:15 p.m.	**U.S. Post-Grant Practice vs. European Opposition** *Chester G. Moore, Ph.D., Baker Donelson, Mandeville, Louisiana*
5:30 p.m. - 6:00 p.m.	Questions and Conclusion
6:00 p.m.	Closing Cocktail Reception

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Intellectual Property 101

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EXPAND YOUR EXPECTATIONS™

IP BASICS

- Copyright
- Trademark
- Patent
- Trade Secrets

Copyrights

What is a copyright?

- A bundle of rights protecting an original work of authorship fixed in any tangible medium of expression

U.S. Constitution, Art. 1, Sec. 8, Cl. 8
17 U.S.C. § 101, *et seq.*

Copyrights

What is copyrightable?

- Literary works
- Musical works (incl. words)
- Dramatic works (incl. music)
- Pantomimes and choreographic works
- Pictorial, graphics and sculptural works
- Motion pictures and audiovisual works
- Sound recordings
- Architectural works
- Computer software

Copyrights

What is *NOT* copyrightable?

- Names
- Titles
- Slogans, short phrases
- Domain names
- Facts, ideas, systems, methods
- Recipes (mere listing of ingredients)
- Clothing designs

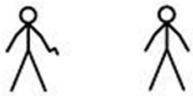
Copyrights

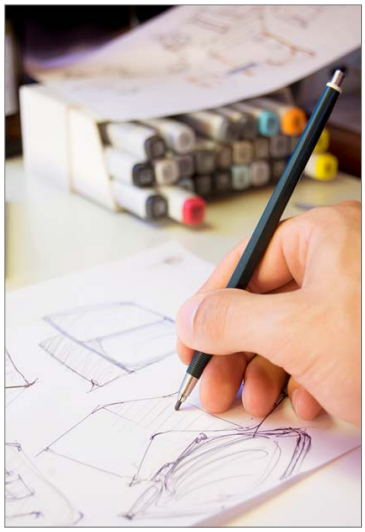
Creation

- Copyright automatically exists as soon as work is created in "fixed form" (tangible medium of expression)
- Registration with U.S. Copyright Office is not required, but brings benefits:
  - Ability to bring infringement action (can possibly use an application only)
  - Timely registration allows recovery of statutory damages and attorneys fees
  - Prima facie evidence of validity of copyright

Copyrights

- To be protected by copyright, a work must contain at least a certain minimum amount of authorship in the form of:
  - original literary,
  - musical,
  - pictorial, or
  - graphic expression





Copyrights

Computer Program

- Set of statements or instructions to be used directly or indirectly in a computer in order to bring about a certain result
- Protects that particular expression of the set of statements or instructions, not what the program does

Copyrights

What is in the bundle of rights?

- Reproduce the work in copies or phonorecords
- Prepare derivative works
- Distribute copies or phonorecords
- Perform the work publicly
- Display the work publicly

Copyrights

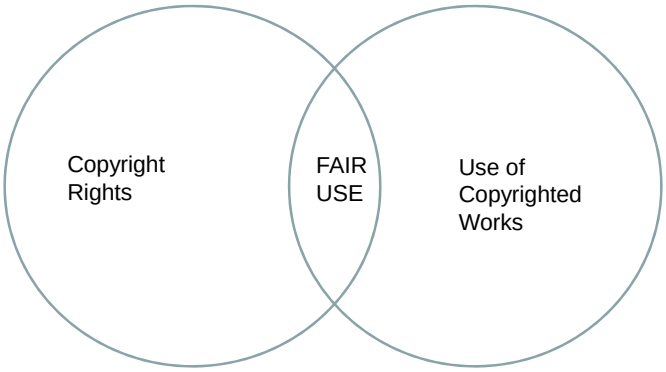
ENFORCEMENT

- Exclusive federal jurisdiction
- Basis for infringement:
  - Access to the infringing work
  - Substantial similarity

TESTS:
- Fragmented literal similarity
- Comprehensive non-literal similarity
- Total concept and feel
- Patterns
- Abstraction-Filtration-Comparison

Copyrights

FAIR USE: Commentary, parody, limited educational use



Copyrights

COMMON **MYTHS** ABOUT FAIR USE

- Acknowledgement of the source makes it fair
- Noncommercial use is fair (so is use by a nonprofit company)
- Lack of a copyright notice means its public domain
- Copying only 10% is fair use
- Fair use is clear cut and easy to determine

Trademarks

A trademark is a symbol used by a person in commerce to indicate the source of the goods and to distinguish them from the goods sold or made by others. The symbol can be a word, phrase, design, image, sound, color, or even fragrance.

Creation upon Use In Commerce

Creation

- Trademark rights conferred by use in commerce
- Registration with U.S. Patent and Trademark Office is not required, but brings benefits:
  - Nationwide notice
  - Can achieve incontestable status
  - Additional remedies & statutory penalties for infringement
- Goals:
  - Consumer Protection
  - Incentives to Users

Trademark

What is a trademark or service mark?

- Any word, name, symbol, device, or combination thereof either used or intended to be used by a person to identify and distinguish goods or services from those of others and to indicate their source of origin

Trademark

Levels of Distinctiveness

- Fanciful or Coined
- Arbitrary
- Suggestive

- Descriptive
- Generic

Trademark

Fanciful or Coined

- Letters that form a word without meaning, has no relation to the product
- Strongest type of mark
- E.g., KODAK, EXXON

Problem: Can become generic

Trademark

Arbitrary

- One or more words whose common meaning has nothing to do with the goods or services being labeled
- Strong mark
- E.g., PARLIAMENT, CAMEL, used for cigarettes

Trademark

Suggestive

- One or more words that hint at or suggest the nature of a product without actually describing it
- Requires a mental step before association between mark and product is understood

Trademark

Descriptive

- Words that merely describe the product or its components or ingredients
- Very weak; protectible as trademark only if it can establish that term has acquired “secondary meaning”
- E.g., World Book (encyclopedia); 5 Minute Massage

Trademark

Generic

- Words that designate the "genus" of the product or what the product is
- Cannot trademark
- E.g., THERMOS, ASPIRIN, CELLOPHAN

Spectrum of Distinctiveness

Levels of Distinctiveness

- Fanciful or Coined
- Arbitrary
- Suggestive

- Descriptive
- Generic

Capable of Registration As "Inherently Distinctive"

Only with "acquired distinctiveness"

Not Registerable

Secondary Meaning

- Used to be descriptive
- Acquired distinctiveness “as a trademark” when the primary significance of Coca-Cola is now the identifier of the source

Goods and Services

- Not “squatter's rights”
- Only registerable for the goods and services for which you seek trademark protection

Stylized / Design Trademarks

- "WALMART"
- "WAL*MART"

WAL*MART

WAL*MART
ALWAYS LOW PRICES.
Always

Walmart
Save money. Live better.

Use it or lose it!

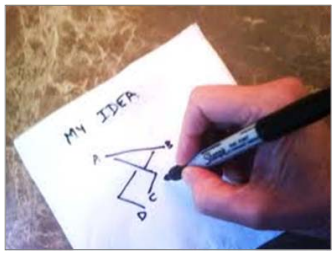
- Trademark law is dependent upon use of the mark

Patents

What is a Patent?

- Set of exclusive rights granted to an inventor for a fixed period of time in exchange for the public disclosure of the invention
- Limited property right

U.S. Const. Article I, Section 8
35 U.S.C. § 101 *et seq.*

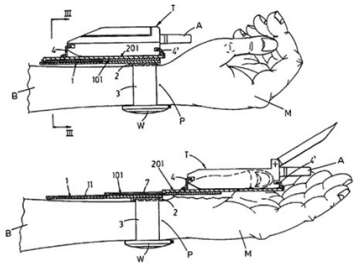


Exclusive Rights

- Right to exclude others from making, using, selling, offering to sell the invention within the U.S., or importing into the U.S.
- Does not give inventor the right to make, use, sell, offer to sell
  - still bound by regulatory restrictions
  - still subject to other prior patents
  - improvements (only the new stuff)

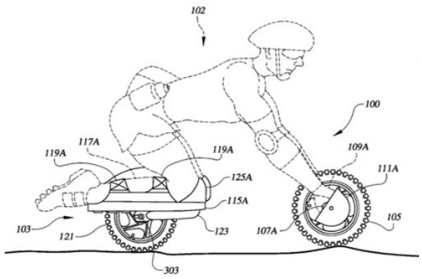
Types of Patents

- Utility – protects a useful device or method, e.g. the way it works or is used; functional and structural features
- Design – protects the ornamental (non-functional) appearance of an article, e.g. the way it looks
- Plant – protects certain types of asexually reproducible plant varieties



Utility Patent Requirements

- Patentable Subject Matter
- Utility (must be useful)
- Novelty (no single patent discloses all of the invention)
- Nonobvious to a person of ordinary skill in the art to which the invention pertains (may be shown by combinations)

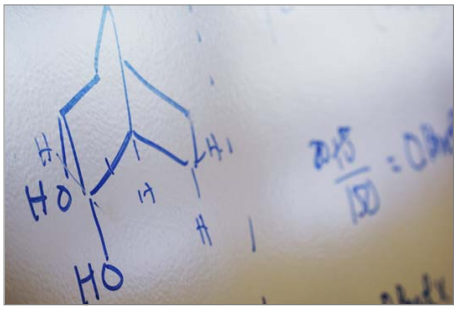


Utility Patents – Subject Matter

- Machine – concrete thing, consisting of parts or of certain devices and combinations of devices
- Manufacture (Article of Manufacture) – production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties or combinations, whether by hand labor or by machinery
- Composition of Matter – composition of two or more substances; chemical compounds; gas, fluid, powder or solid
- Process – act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing; methods

Patentable Subject Matter

- CANNOT obtain a patent for:
  - scientific truths, laws of nature
  - mathematical expressions
  - algorithms
  - abstract ideas
  - physical phenomena



Novelty

- Inventor Can Destroy Novelty

  - public use or disclosure of invention

  - prior sales or offers for sale of invention

  U.S. – more than 1 year prior to filing
  Foreign – absolute novelty bar

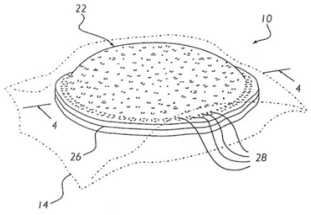
Unlike copyrights and trademarks, you must:

(1) timely file application with the USPTO; and

(2) undergo examination and have patent issued

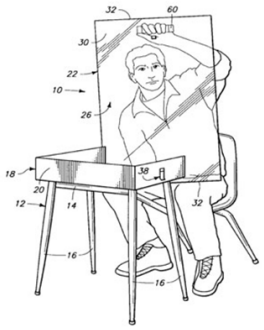
Ownership

- In U.S., only individuals can apply for a patent (not corporations, similar entities)
- Inventors can assign the patent to any entity
- Each inventor owns full rights to invention without an obligation to the other inventors
- *BOTTOM LINE: Consolidate ownership; get obligation to assign IP rights in employment agreement!*



Provisional Patent Application

- Low cost and quick
- No claims required
- No particular format
- Provides earlier effective filing date, permits use of "patent pending" status
- Not examined; only a place holder
- Does not issue into a patent
- Must file nonprovisional utility application within 1 year



Licensing

- Contract where parties agree to the terms and conditions under which certain rights in the invention/patent are granted (manufacturing, selling, etc.)
- Exclusive or nonexclusive
- Field of use restrictions (industries, markets, uses, etc.)
- Geographical restrictions
- Royalties or other compensation (highly variable)

Enforcement / Infringement

- To infringe a patent claim, all elements of a claim must be present in the accused device or method
- Patent owner is entitled to a claim scope commensurate with the details of the specification and their "reasonable equivalents"
- Patent validity will always be contested:
  - Failure to consider material prior art
  - Concessions made during prosecution (estoppel)
  - Inequitable conduct

Practical Patent Advice

Conception and Reduction to Practice

- Write all ideas down with dates of conception; can avert undeserved co-inventorship
- Keep a written record of changes and improvements
- Identify all collaborators with brief description of contribution to the effort; missing co-inventors can cause expense, broken deals, and invalidity
- Manuals, grant proposals, etc., are very helpful; great basis for patent application specification
- Store in a safe place, like in the “cloud”; think Katrina and Rita…

Secrecy

- Secure strong nondisclosure agreements (NDAs) with other parties, but limit the number of NDA’s; not everyone is worth it or trustworthy
- Should contain assignment language to avert co-ownership problems with co-inventors; may meet with some resistance, but the alternative is worse with an “unintended partner”
- Term should be for at least enough time to get past a long patent prosecution (assuming no publication at 18 months); typically 3-5 years

Search

- Searching is optional, BUT:
  - Prevents throwing good money out after bad
  - Knowing prior art is critical for drafting persuasive specifications and claims
  - Anticipate possible rejections
  - Trade journals and other technical publications must be considered in rapidly evolving technologies (no patent records); think software, pharma, solar, nanotechnology, etc.

Provisional Applications

- Use provisional applications sparingly and wisely
  - Delays in examination; only a place holder for up to 12 months
  - Added costs
  - Failure to adequately support claims in later nonprovisional application
  - May jeopardize foreign rights if too lean an initial disclosure, because the same 12 month deadline applies
  - Difficult to avoid with Patent Reform Act; file early and often

Filing Strategy

- Develop a strategy for protecting a portfolio of ideas (alternate embodiments, future developments, etc.); build the spider web
- FOCUS: “all eggs in one basket” rarely makes good sense; only one invention per application; restriction requirements and election of species will cause divisionals anyway
- Filing decisions and claim drafting should factor in how products will be marketed; think system vs. method, and how prospective licensees may want one, but not the other

Organization and Priorities

- Patents are business tools
- Treat each idea/application as an asset to be valued in a transaction; how can each asset be monetized?
- Many early stage companies rely almost entirely on IP assets (rather than revenue); even a portfolio of pending applications preserves IP rights for prospective purchasers, and may be important to future investors
- Let licensing and enforcement considerations drive the discussion regarding claims, including which divisionals and CIP’s may be desirable

Disclose Prior Art

- Affirmative duty of disclosure of known prior art to the USPTO; only if "material to the examination"
- No "hiding the ball"; full disclosure is part of the deal between you (patent owner), the public (progress of science and the useful arts), and the federal court system (enforcement of your rights)
- Potential invalidity for failure to disclose prior art
- Includes prior art from foreign patent prosecutions which may not have been considered in the U.S.
- Avoids inequitable conduct defense by infringers

Defense

- Patents are a sword, not a shield
  - Patents provide only an exclusionary right; no rights to do anything, only to stop others from doing what's in the patent
  - No relevance to infringement of prior patents; just because you have a patent, you can still be sued for infringement
  - Know competitor's patent portfolio; map out claims for "design around" efforts; think Venn diagrams
  - Possible use of patents as a basis for counterclaims and cross-licensing to settle disputes

International Patents

- U.S. is a signatory to several multinational patent treaties; preserve international rights (national, regional, PCT) before 12 months from initial application
  - But will depend on U.S. non-publication request; if non-publication request is filed, then filing foreign will jeopardize U.S. application
  - Add “outlier” countries that may be important based on market and manufacturing, e.g. Taiwan, and some South American, African, and Middle East countries
  - PCT search results are almost always faster than U.S. examiners
  - Budget carefully and prioritize; can be very expensive

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THANK YOU!

Intellectual Property 101

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Dealing with Difficult Examiners: Getting to Allowance

Richard E. L. Henderson
David L. Vanik

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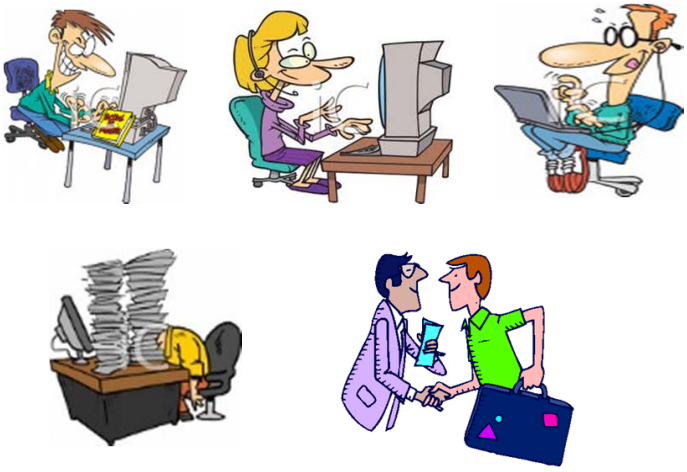
Overview

I. Establishing a Relationship with the Examiner
- Section § 1.3 of the Patent Rules
- Examiner Interaction
- The Benefits of Examiner Interviews

II. Navigating the USPTO Hierarchy
- Examiner Hierarchy
- Quality Assurance and Examiner Performance Appraisal plan (PAP)
- Procedural tools for challenging Examiners

Establishing a Relationship with the Examiner



Section § 1.3 of the Patent Rules

- **§ 1.3 Business to be conducted with decorum and courtesy**

  Applicants and their attorneys or agents are required to conduct their business with the United States Patent and Trademark Office with decorum and courtesy.

Establishing a Relationship with the Examiner

- Examiner interaction
  - Exercising patience and professionalism
  - Being honest and "up-front" (for example, by using objective facts to support legally sound arguments)
  - Returning an Examiner's telephone call in a timely manner

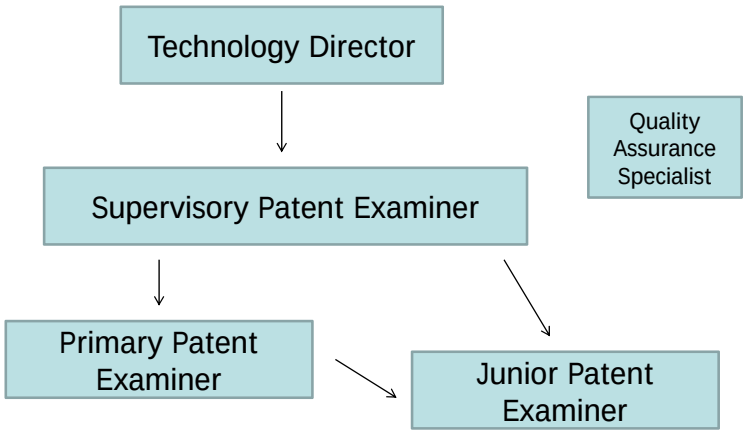
Establishing a Relationship with the Examiner - Interviews

- Interviews
  - Telephone vs. in-person interviews
  - Effectiveness of interviews in establishing a relationship with the Examiner

Establishing a Relationship with the Examiner - Interviews

- Some advantages of a USPTO interview
  - Placing a "face" with an application
  - Accountability of a junior Examiner with a Primary Examiner/SPE
  - Helping to foster the Examiner/Applicant relationship

Navigating through the USPTO Hierarchy



Quality Assurance Specialists

MPEP 1308.03 Quality Review Program for Examined Patent Applications

- The Office of Patent Quality Assurance administers a program for reviewing the quality of the examination of patent applications. The general purpose of the program is to improve patent quality and increase the likelihood of patents being found to be valid.

- The quality review is conducted by Review Quality Assurance Specialists on a randomly selected sample of allowed applications from each examiner.

Examiner Performance Appraisal Plan (PAP)

- **Production:**
  - Examiners are required to achieve a certain number of "counts" per bi-week.
- **Work Flow:**
  - Revamping the workflow element to provide examiners more opportunities to use their professional discretion to manage their own workflow.
- **Quality:**
  - Revising the performance standards to include a single quality element for all examiners—increasing the focus on examination quality and improving the transparency of how quality is measured; and
  - Establishing a "Stakeholder Interaction" element that emphasizes routine use of interviews to facilitate compact prosecution and timely responsiveness to requests for personal interviews.

Pre-Appeal vs. Appeal - Factors to consider

Pre-Appeal	Pre-Appeal
• quick turnaround time	• usually about 15 months for BPAI to consider
• can quickly dispose of clearly incorrect rejections	• potentially a more comprehensive avenue for legal arguments
• helps to sharpen arguments for appeal	• can comprehensively argue each claim separately
• pre-appeal conference	• patentability conference

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Search Issues Under the America Invents Act

Presented by:
Drew Lowery, Ph.D.
Group Leader – Biotechnology
Global Prior Art

March 20, 2012

GLOBAL PRIOR ART, INC.

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Global Prior Art at a Glance

Our in-depth knowledge of cutting edge technologies, combined with nearly three decades of IP-related experience distinguishes Global Prior Art as a worldwide leader in IP analysis.

- Freedom-to-Operate Searches
- Patent Validity and Invalidity Studies
- IP Due Diligence for Licensing & Acquisition Opportunities
- State of the Art Reviews
- IP Landscape Analysis

Global's Technical Specialties

Global brings together an interdisciplinary team that has broad technical expertise and specialized training in each of these technology areas:

Engineering & Electronics	Life Science Technologies
Semiconductors & Electronics	Medical Devices
Network Engineering & Data Communications	Biotechnology
Software & Computer Science	Pharmaceuticals
Mechanical Engineering & Manufacturing	Drug Delivery
E-Commerce & Business Processes	Medical Electronics

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America Invents Act Search Issues

- Supplemental Examination Procedure
- Third Party Prior Art Submission
- Post Grant Review

Prior Art Based Patent Searches

Your Inventions

- Patentability pre-filing
- Patentability during prosecution
  modified by Supplemental Examination Procedure
- Validity in preparation for enforcement or re-exam
  Supplemental Examination Procedure

Competitor's Inventions

- Patentability during prosecution
  Third Party Prior Art Submission
- Validity post grant (for FTO opinion, re-exam, etc.)
  Post Grant Review
- Validity after you receive notice of infringement

Supplemental Examination Procedure

Supplemental Examination Procedure

Pre-AIA

All potentially relevant prior art that the applicant was aware of had to be in the IDS form filed before grant.

Post-AIA (effective from September 2012)

The America Invents Act creates a new procedure allowing a patent owner to request that the USPTO carry out a supplemental examination of a patent to "consider, reconsider or correct information believed to be relevant to the patent." This new procedure allows applicants to place additional art in front of examiners after grant. These could be documents that they newly became aware of or otherwise forgot to submit previously, and submitting them prevents a finding of inequitable conduct related to this art.

Supplemental Examination Procedure

You should commission a search because…

Disclosing art yourself allows you to control the process and make arguments with the USPTO examiner as to why your invention overcomes the art.

Disclosing art yourself prevents a competitor from having the first chance to characterize the art, and makes their case more difficult because the USPTO is already on record as having agreed that your invention overcomes the art.

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Third Party Prior Art Submission

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Third Party Prior Art Submission

Pre-AIA

Third-Party prior art submission has always been accepted by the USPTO for published applications that are still in prosecution, though there was no requirement for the examiner to consider submitted art.

The submitter was not allowed to make any arguments regarding the submitted documents.

Thus, this procedure was rarely used by competitors and was mainly a mechanism for the public to submit art.

Third Party Prior Art Submission

Post-AIA (effective from September 2012)

The America Invents Act adds a new third-party preissuance submission law that requires that any submission must set forth a concise description of the asserted relevance of each submitted document.

This gives competitors a compelling reason to submit art since they can directly state why the art invalidates or otherwise limits the claim scope of the patent.

The timeframe remains limited as all art must be submitted in a restricted period around the publication of the application and the first action by the USPTO examiner.

Third Party Prior Art Submission

You should commission a search because…

Rather than arguing in court where you have millions of dollars on the line and there is an assumption of validity you can pre-empt the patent ever getting granted in the first place.

Post Grant Review

Post Grant Review

Pre-AIA

USPTO does not have a simple Post Grant Review system. Ex parte and inter partes reexaminations are the only options.

Post-AIA (effective from September 2012)

Post Grant Review is a completely new addition to the patent laws added in the America Invents Act, and it goes into effect later this year. It is modeled somewhat after the European Opposition laws that allow for a post grant opposition.

This notice is currently given on the face of every EP patent.

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Post Grant Review

Post-AIA More Details (effective from September 2012)

The America Invents Act allows for a 9 month window post-grant for new prior art to be submitted by third parties. All evidence including any arguments regarding the relevance of the submitted prior art must be included with the original submission, and the findings of the USPTO have to be completed within one year.

Ex parte and inter partes reexaminations are still available at later dates, but carry significantly higher costs and timeframes than Post Grant Review.

Post Grant Review

You should commission a search because…

As with third-party art submission rather than arguing in court where you have millions of dollars on the line you can attempt to get the patent invalidated immediately without the expense and complications of litigation or even inter partes reexamination.

Monitoring Competitor's Patents

Monitoring Competitor's Patents

For Third Party Prior Art Submission and Post Grant Review you first have to find out in a timely manner that there is an application or patent of concern to your business.

This can be done through the use of a series of alerts that indicate when a patent publication has come out by a competitor. The new documents will need to be rapidly reviewed by inside or outside counsel and potentially upper management to decide on a course of action.

Even if such a system were in place it would not catch documents from new entrants into the space. These would only be caught through a continual monitoring of your technological space by a professional searcher.

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Setting Up a High Quality, Cost Effective Search

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Setting Up a High Quality, Cost Effective Search

I. Who

- Considerations for Selecting a Search Partner
  - What is their technical background?
  - What is their searching expertise?
  - What is their ability to leverage relevant sources and documents?

II. Where

- Determining the Right Geographical Locations to Cover
  - There are many place in the world to search
  - Don't overlook the value of a comprehensive English-language search
  - Consider the market drivers for the particular technology of interest

III. What

- Leveraging the Best Sources
  - Patents if technology driven by company innovation
  - Technical literature if technology driven by academic innovation
  - More obscure, harder to access sources like conferences, theses, advertisements

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Case Study Highlighting Effective Searching Techniques

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ATM Search

Focus:

An ATM system where the user is instructed to go to another location, such as a casino cage, when a limit is reached

Challenge:

The client has conducted a search of U.S. literature and patents which did not yield any relevant art.

Solution:

Analysis of the previous search concluded that the search covered literature readily available rather than literature which is relevant.

Recommendation:

- Cover core U.S. literature germane to ATM technology and gambling
- Follow up leads on promising implementations at leading gambling library

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ATM Search – Core Sources

Exhibit:

U.S. Literature Coverage List on ATM Systems and Gambling

Publications

- Casino Executive
- Casino Journal, Nevada
- Gaming Products & Services Magazine
- Gaming Research and Review Journal
- Gaming Today
- Journal of Gambling Studies

Casinos use many methods of cash access: ATMs, check cashing and credit card advances, as well as change carts for customers on the floor. The companies that provide these services vary greatly and casino managers must stay on top of changes in the industry to ensure the best service to their customers.

Databases

- Gaming Studies Research Center @ the University of Nevada – Las Vegas

Cover the Core Sources and Avoid Marginalization

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Introduction to Global Prior Art

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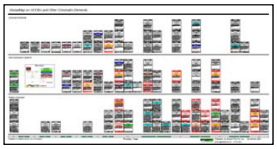
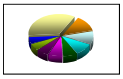
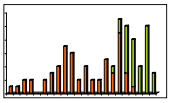
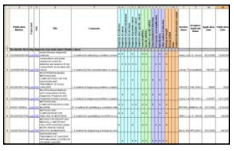
Global Prior Art's Project Types

- Prior Art
- Freedom to Operate
- Patentability
- Accelerated Exams
- IP Landscape
- State of the Art
- Due Diligence



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Global Prior Art's Resources

• Medical & Technical Journals • Scientific Databases	→ • Local libraries (Harvard, MIT Tufts & others) are unrivaled resources
• US Patents	→ • An in-house P9 system replicates the USPTO system
• Foreign Literature • Foreign Patents	→ • Analysts fluent in Japanese, Chinese, Russian, & German • Full-text searches conducted in the original language

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Global Prior Art's Life Science Experts

Senior Staff

Gerald Sewack, Ph.D. Senior Vice President Life Sciences

BIOTECHNOLOGY and PHARMACEUTICALS:
Drew Lowery, Ph.D. (therapeutic proteins, oncology, metabolomics, arrays)

CHEMISTRY and MATERIALS:
Maxim Pometun, Ph.D. (small molecules, drug delivery, petrochemicals, polymers)

MEDICAL DEVICES:
Jesse Goodwin, Ph.D. (orthopedic devices, surgical tools, vascular valve repair)

Selected Additional Experts

David Adamovich, Ph.D. (molecular biology, microbiology, genomics)
Olga Finikova, Ph.D. (synthetic organic chemistry, small molecules, natural products)
Jeannette Fiala, Ph.D. (antibody technologies, diagnostic assays, nucleic acids)
Daniel Neuman, Ph.D. (organic chemistry, small molecules, therapeutic formulations)
Ken Statler, Ph.D. (ablative surgical devices, biomaterials, neurostimulation)

Foreign Language Experts

Chie Nakamura, Ph.D. - Japanese
Melanie Estrada, Ph.D. – German
Vadim Demidov, Ph.D. - Russian
Lu Zhe, B.S. - Chinese

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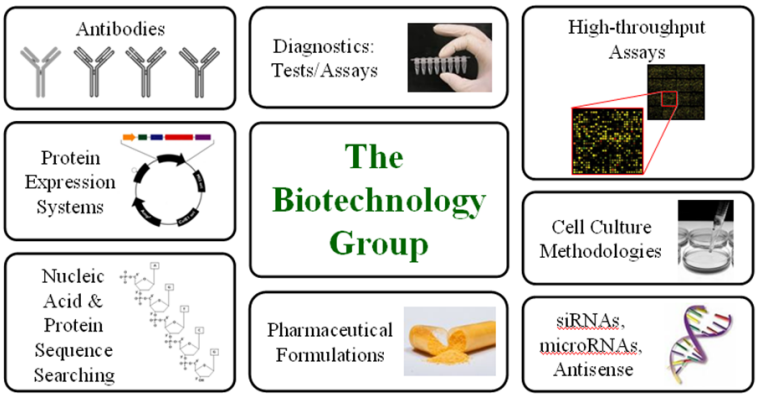
Life Science Group Expertise



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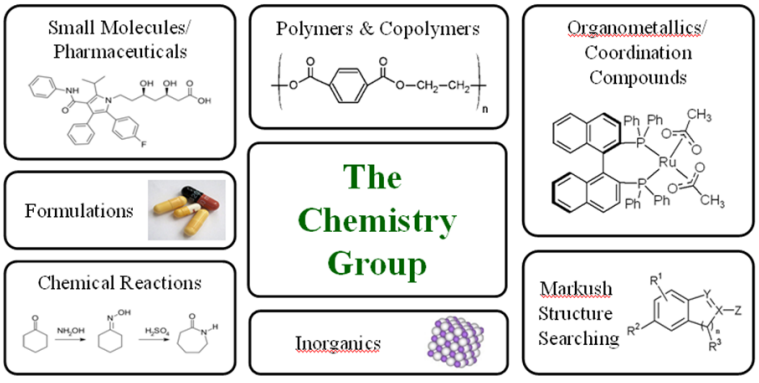
Life Science Group Expertise



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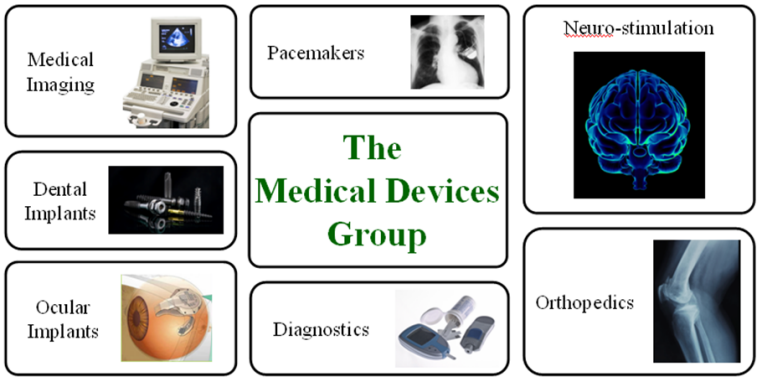
Life Science Group Expertise



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The People of Global Prior Art

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BEARMAN, CALDWELL & BERKOWITZ, PC

Mergers & Acquisitions and Licensing Panel Discussion

Moderator: David Rieveschl
Baker, Donelson, Bearman, Caldwell & Berkowitz, PC
New Orleans, Louisiana
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EXPAND YOUR EXPECTATIONS℠

International Trade and Transactions

Entering the US Market and Hot Trade Topics

BAKER DONELSON IP SYMPOSIUM
March 20, 2012

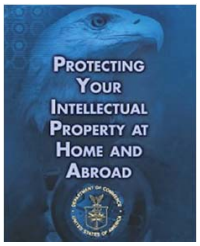
Presenter: Hena Schommer

BAKER DONELSON
BEARMAN, CALDWELL & BERKOWITZ, PC

EXPAND YOUR EXPECTATIONS™

Presentation Outline

- General Introduction to Entering the US Market
- Industry Specific Import Regulations: FDA Overview
- Hot Topics to be aware of in international trade & transactions



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General Overview for Entering the US Market

Key topics when importing or exporting products into the US:

- Responsible Departments & Agencies for Imports or Exports
- U.S. Export Overview
- U.S. Import Overview
- Recordkeeping
- Informed Compliance – Ignorance is no Excuse

3

U.S. Departments That Regulate Imports & Exports

U.S. Customs and Border Protection (CBP)
decision maker on all goods entering and leaving U.S. territory http://www.cbp.gov/

U.S. Department of Commerce, Bureau of Industry and Security (BIS)
governs commercial and dual-use items and technology, including software and encryption items. http://www.bis.doc.gov/

U.S .Department of State, Directorate of Defense Trade Controls (DDTC)
governs defense and military use articles and services and technical Data, including space and satellite related articles. http://www.pmddtc.state.gov/

U.S. Department of Treasury, Office of Foreign Assets Control (OFAC)
implements the primary sanctions regime and imposes economic and trade sanctions on designated countries, entities, and persons. http://www.treasury.gov/

Exports: The Four Questions

1. What is the item's intended use for export?
2. Where is it going? What is the ultimate destination?
3. Who will receive it? Who is the end-user?
4. What will they do with it? Are there multiple uses?

Exports: Classification of Products

Source of Classifications:

- Commerce Control List (CCL)
- United States Munitions List (USML)

Purpose: The classification determines the level of controls for each product

Three ways to classify:

1. Get it in writing from the manufacturer
2. Request a classification
3. Self-classify using the four questions

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Exports: BIS/DDTC

Commerce Department (BIS)

- "Dual Use" Commercial/Military
- Controlled items appear on Commerce Control List
- A number of exceptions available
- Examples of EAR controlled items:
  - semiconductors
  - telecommunications
  - high speed computers
  - manufacturing equipment

State Department (DDTC)

- Designed, modified, adapted, or configured for military/space
- Controlled items appear on the United States Munitions List
- Very few exceptions available; license typically required
- Examples of ITAR controlled items:
  - high altitude GPS receivers
  - cryptographic electronics
  - satellite components
  - guns over .50 caliber

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Imports: The Four Questions

1. What is the classification of the goods or products entering the U.S.?
2. What is the value of the goods? How is this value determined?
3. What is the country of origin of the goods for duty purposes, marking purposes, special treatment purposes?
4. What U.S. departments or agencies regulate my goods or products? Do they have special registration or licensing requirements for imports?

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Imports: Classification of Products

Source of Classifications:

- U.S. Harmonized Tariff Schedule (HTS)

Purpose:

- Determines duties paid on imported goods
- Determines applicability of quotas/antidumping duties/countervailing duties to imported goods

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Imports: Value of Goods

Determining the Value:

- Tariff/Duty rates: calculated as a percentage of the goods' value
- Calculation of the Value of Goods
  - Transaction Value: The total price paid to the foreign vendor when it is sold for exportation to the U.S., excluding actual international freight and insurance costs, but including commissions, royalties, assists, proceeds, and packing
  - Transaction Value of Similar Merchandise
  - Transaction Value of Identical Merchadise
  - Other Valuation Methods

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Imports: Country of Origin

Determining Country of Origin:

- Bases: country of manufacture, production, or growth of the good
- Marking: mark products with accurate legal definition of the country of origin, legibly in English
- Special Treatment: determines applicability of special treatment/free trade programs

Transshipment: The act of shipping goods to an intermediate destination prior to reaching their ultimate end-use can be used to illegitimately disguise country of origin to avert high duties or import restrictions

Penalties: Loss of import privileges; seizure of imported merchandise; civil fines

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Record Keeping Requirements – Imports & Exports

- Applies to:
  - Owners, importers, exporters consignees, importers of record, declaration filers, entry filers, licensees
- Records to be kept:
  - Those prepared for the entry of merchandise (bills of lading, declarations of entry, importers of record, countries of origin), documents regarding exports, due diligence requirements, license determinations
- How long must records be kept? (generally)
  - Five years from the date of entry; or
  - Five years from the date of "activity" which required the maintenance of records
- Penalties
  - Willful violation
  - Negligence

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Informed Compliance – Ignorance Is No Excuse

Document Compliance:

- Conduct due diligence - on the parties they are purchasing from or the end-user they are shipping too
- Use reasonable care - to accurately report the classification, value and country of origin of the imported goods or to accurately self-classify and document classification process for exports
- Demonstrate in-house training and formal compliance review - on a regular basis for either imports or exports to demonstrate organizational commitment to compliance
- Well-Informed/Educated on Relevant Issues:
  - Follow all recordkeeping requirements
  - Be aware of IP rights and any trade restrictions that may affect the import/export product(s)

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Industry Specific Import/Export Regulations: The FDA

The U.S. Food and Drug Administration (FDA) Has Broad Authority Over Import and Exports in the following areas:

- The import and export of medical devices
- The importation of drugs
- The right of refusal of goods entering the U.S. market

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The FDA: Basic Rules

The Import and Export of Medical Devices:

- Foreign manufacturers must meet applicable U.S. medical device regulations in order to import devices into the U.S. Requirements include registration of establishment, listing of devices, manufacturing in accordance with the quality system regulation, medical device reporting of adverse events, and any other FDA

The Importation of Drugs:

- Burden is placed on the importer to prove that the drug to be imported is approved by the FDA. The FDA prohibits the interstate shipment (which includes importation) of unapproved new drugs. The importation of drugs that lack FDA approval violates U.S. law.

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The FDA: Broad Power to Prevent Entry

Refusal Authority

"If it ***appears*** from the examination of such samples ***or otherwise*** that:

- such article has been manufactured, processed, or packed under unsanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to U.S.
- such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or
- such article is adulterated, misbranded, or in violation of U.S. law or prohibited from introduction or delivery for introduction into interstate commerce then such article shall be refused admission."

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The FDA: Beyond U.S. Borders

Memoranda of Understanding (MOUs).

- FDA has negotiated more than 50 MOUs that commit the governments of the exporting countries to make sure that their products destined for the United States meet U.S. standards.

Inspections.

- FDA's specialists inspect foreign facilities that export food, medications and other critical regulated products to the U.S. Approximately 1000 of these inspections are done each year.

Training.

- FDA trains its regulatory counterparts in exporting countries in U.S. public health requirements and in methods.

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Hot Topics in IP Regarding International Trade

- **White House Office of the U.S. Intellectual Property Enforcement Strategy**
- **Customs and Border Patrol IP Regulation Enforcement Program**
- **Foreign Corrupt Practices Act**

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White House Office of the U.S. Intellectual Property Enforcement Coordinator

Description:

- U.S. Government-wide working group to prevent U.S. Government purchase and continued commerce of counterfeit products
- Using U.S. international negotiating power and cooperation to discourage counterfeit product by other countries and progress made
- Report on efforts of different U.S. Government departments and agencies to discourage IP rights violations

Example: President Obama calling out China's record on intellectual property protections of U.S. products going to China. Negotiations being completed late November 2011 by officials from the U.S. Trade Representative, Department of Commerce and Agriculture to secure commitments from China of on key IP issues.

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CBP Intellectual Property Regulation Enforcement Program

Mission: CBP targets and seizes imports of counterfeit and pirated goods, and enforces exclusion orders on patent-infringing and other IPR violative goods.

This multilayered strategic approach:

- Targets shipments of IPR infringing goods
- Audits infringing importers
- Provides training and legal guidance on IPR enforcement
- Seizes products
- Issues civil penalties and refers information to the Justice Department for criminal investigations

Resources: IP Rights E-recordation (IPRR) online system to record and protect a trademark, which is added to a CBP database, the ability to provide CBP resources and training to protect your product from IP Infringement.

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What Can You Do As A Company to Protect Your IP?

- Register your IPR Trademark with U.S. CBP
- Develop US product identification materials for CBP
- Share intelligence on violators and suspect shipments with CBP officials

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The Foreign Corrupt Practices Act (FCPA)

- Increase in FCPA prosecutions
- Focus on a written compliance plan
- Training
- Due diligence
- Voluntary disclosure

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Question and Answer

Thank you !

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10 THINGS YOU NEED TO KNOW ABOUT PATENT REFORM

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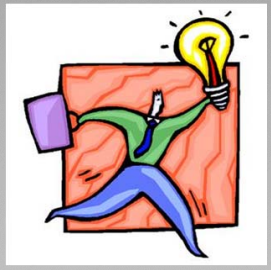
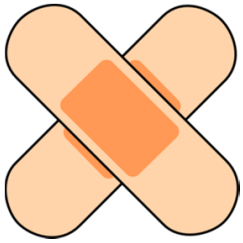


EXPAND YOUR EXPECTATIONS™

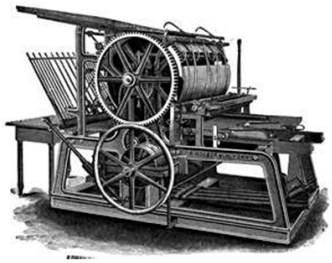
Patent Reform

- Signed by President Obama on Sept. 16th
- Melange of changes (major and minor)



1. It's Not Really "First-to-File"

- "First-to-Publish" can beat "First-to-File"
- Interaction of new Sections 102(a), (b)



Section 102(a): First-to-File

- Entitled to patent unless:

(1) patented, described in printed publication, in public use, on sale, or otherwise available to public before effective filing date (subject to one-year grace period), or

(2) described in patent or patent application by another effectively filed before effective filing date

Section 102(b)(1): 1-Year Grace Period

- Disclosure made < 1 year before filing is not prior art under 102(a)(1) if:
  - (1) disclosure was made by inventor, or another who obtained subject matter from inventor, or
  - (2) inventor or another who obtained from inventor had publicly disclosed the subject matter before the disclosure in question

Section 102(b)(2): Prior Art Disclosure

- Disclosure in patent or application is not prior art under 102(a)(2) if:
  - (1) subject matter disclosed obtained from inventor, or
  - (2) inventor or another who obtained from inventor had publicly disclosed the subject matter earlier, or
  - (3) both owned or under obligation to assign to same person

"First-to-File"

- INVENTOR A
  - Jan: invents
  - July: file patent app.
- INVENTOR B
  - Feb: invents
  - Dec: file patent app.

Same result even if B invents first

"First-to-Publish"

- INVENTOR A
  - Jan: invents
  - June: publishes article
  - July: file patent app.
- INVENTOR B
  - Feb: invents
  - April: publishes article
  - Dec: file patent app.

2. Don't Count on Publishing

- "Absolute Novelty" bar
- Will lose foreign filing rights

File Early, File Often!

Defensive Publication: not seeking patent protection, but protection from patenting

3. Prior Art Hurdles Are Higher

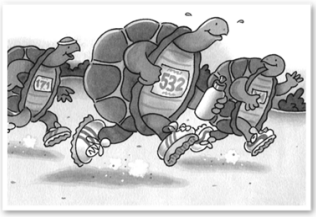
- "On sale" removed from grace period
- Public use no longer limited to U.S.
- Foreign patent applications will count for priority dates (i.e., for "effective filing date")

4. Don't Wait on FTF

- FTF applies to applications filed on or after Mar. 16, 2013 BUT....
  - can be affected by third-party publications on or after Mar. 16, 2012
  - changes in grace period

5. File New Apps Before FTF

- File before Mar. 16, 2013
  - new apps & CIPs
- Avoid broader definition of prior art
- Can still swear behind third party prior art
- Avoid post grant review



6. New Avenues for Attack

- Post Grant Review ("opposition")
  - 9-mo. window
  - broader than re-exam
- Inter Partes Review
  - amended IP Re-exam
  - new standard (reasonable likelihood)
- Pre-Issuance Submissions

7. Supplemental Examination

- Similar to *Ex Parte* Re-exam, but not limited to patents and publications
- Patent owner can address any validity issues uncovered after patent is granted
- Patent owner can purge inequitable conduct
  - must be done before any attempt is made to enforce patent, or before owner receives a notice of invalidity
  - excludes substantial fraud

8. Derivation Is The New Interference

- PTO or civil action
- Resolves whether earlier inventor derived claimed invention from an inventor in later-filed application
- Good reason to keep inventor's notebooks and other documents establishing independent research and development of claimed subject matter

9. Mixed Bag re Litigation

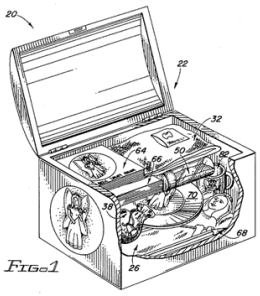
- False Marking Cases
- Prior Commercial Use Defense
- Best Mode
- Attorney Opinions
- Joinder of Multiple Defendants
- Jurisdiction
- Venue
- Removal

False Marking Cases

- *Qui tam* actions based on false marking eliminated
- Third party must show actual economic harm
  - damages limited to actual economic harm
- Marking product with expired patent number no longer false marking
- Applies immediately to all pending and future actions

Prior Commercial Use Defense

- Section 273 expanded beyond just business methods
- Includes machines, articles of manufacture, and compositions of matter used in manufacturing or commercial process
  - internal commercial use
  - arm's length sale or commercial transfer of a useful end result of such a commercial use



Prior Commercial Use Defense

- At least 1 year prior to effective filing date or public disclosure date of claimed invention
- Defense has burden of proof
  - clear and convincing evidence

Prior Commercial Use Defense

- Applies to entity that performed or directed the performance of commercial use, or entity that controls, is controlled by, or is under common control with that entity
- Not transferrable, except as part of transfer of entire enterprise or line of business
  - cannot expand sites

Attorney Opinions

- Failure of defendant to either obtain opinion of counsel re patent or to present such advice at trial may not be used to prove willful infringement or intent to induce

Federal Joinder

- No longer easy to sue a laundry list of defendants
- Join only if allegations arise out of common occurrence, transactions, or series of such, and there are common issues of fact
  - insufficient merely to claim infringement of same patent

10. Patents Not Easier or Cheaper

- Lots of uncertainty with disclosure, derivation and first-to-publish
- Narrower one-year grace period
- Broader prior art
- Post Grant Review

USER-OPERATED AMUSEMENT APPARATUS FOR KICKING THE USER'S BUTTOCKS

Armstrong, US 6,293,874 (Sep. 25, 2001)

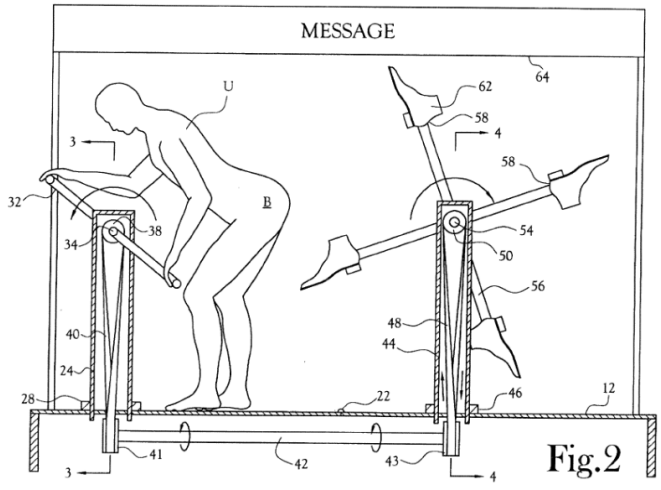


Fig.2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Supreme Court Rejects Prometheus Method Claims

W. Edward Ramage

March 20, 2011

As a follow-up to its recent *Bilski* decision, and continuing its focus on the question of patentable subject matter, the U.S. Supreme Court today issued its decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* In a unanimous decision, the Supreme Court held that method claims that involved administering a drug to a patient and determining the effect were not patentable subject matter. The Court held that the correlation between the drug being administered and the concentrations of certain metabolites in the blood of the patient was not itself patentable as a "law of nature," and the claimed processes, while not natural laws themselves, did not sufficiently transform the nature of the claims.

Prometheus Laboratories is the exclusive licensee of two patents claiming the use of thiopurine drugs to treat autoimmune diseases. When ingested, the drugs are metabolized and produce metabolites in the bloodstream of the patient. The claims are directed to processes that identify correlations between metabolite levels and likely harm or ineffectiveness of the drug with regard to that patient. The claims each recite an administering step (the physician administers the drug to the patient), a determining step (the physician measures the resulting metabolite levels), and a "wherein" step describing the metabolite concentrations above which there is a likelihood of harmful side effects, and below which there is a likelihood of ineffectiveness. The physician is informed that concentrations above or below either threshold indicate a need to decrease or increase the drug dosage.

Mayo announced that it intended to sell and market a similar diagnostic test. Prometheus sued Mayo for patent infringement, and Mayo challenged the validity of the claims. The District Court found that the claims effectively claimed natural laws or phenomena, and declared the claims invalid. On appeal, the Federal Circuit Court of Appeals initially reversed, holding that the claims met the "transformation" element of the machine-or-transformation test which had been developed as a means for testing patent eligibility. The case was remanded by the Supreme Court for further consideration in light of its *Bilski* decision, and the Federal Circuit reaffirmed its earlier conclusion. In its decision today, the Supreme Court reversed.

The Court's starting point was that the relationship between the metabolite concentrations and the likelihood that the thiopurine drug dosage would be harmful or ineffective is a "law of nature," and thus not patentable. The claimed processes were applications of a law of nature, and would not be patentable unless they have additional features that provide practical assurance that the processes are genuine applications of those laws, rather than an attempt to monopolize the correlations. In this case, the Court determined that none of the steps of the method claims met this standard.

This decision brings into question the validity of similar claims in many patents already issued, and will have an immediate impact on pending patent applications. It also may have some bearing on the issue of the patentability of parts of the human genome, an issue that the Supreme Court may consider this coming term in the *Myriad Genetics* case.

If you have any questions or want to discuss how this decision could impact your business, contact your Baker Donelson attorney or one of the attorneys in our Intellectual Property Group.

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

MAYO COLLABORATIVE SERVICES, DBA MAYO MEDICAL LABORATORIES, ET AL. *v.* PROMETHEUS LABORATORIES, INC.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 10–1150. Argued December 7, 2011—Decided March 20, 2012

Although "laws of nature, natural phenomena, and abstract ideas" are not patentable subject matter under §101 of the Patent Act, *Diamond* v. *Diehr*, 450 U. S. 175, 185, "an *application* of a law of nature . . . to a known structure or process may [deserve] patent protection," *id.,* at 187. But to transform an unpatentable law of nature into a patent-eligible application of such a law, a patent must do more than simply state the law of nature while adding the words "apply it." See, *e.g., Gottschalk* v. *Benson*, 409 U. S. 63, 71–72. It must limit its reach to a particular, inventive application of the law.

Respondent, Prometheus Laboratories, Inc. (Prometheus), is the sole and exclusive licensee of the two patents at issue, which concern the use of thiopurine drugs to treat autoimmune diseases. When ingested, the body metabolizes the drugs, producing metabolites in the bloodstream. Because patients metabolize these drugs differently, doctors have found it difficult to determine whether a particular patient's dose is too high, risking harmful side effects, or too low, and so likely ineffective. The patent claims here set forth processes embodying researchers' findings that identify correlations between metabolite levels and likely harm or ineffectiveness with precision. Each claim recites (1) an "administering" step—instructing a doctor to administer the drug to his patient—(2) a "determining" step—telling the doctor to measure the resulting metabolite levels in the patient's blood—and (3) a "wherein" step—describing the metabolite concentrations above which there is a likelihood of harmful side-effects and below which it is likely that the drug dosage is ineffective, and informing the doctor that metabolite concentrations above or below

these thresholds "indicate a need" to decrease or increase (respectively) the drug dosage.

Petitioners Mayo Collaborative Services and Mayo Clinic Rochester (Mayo) bought and used diagnostic tests based on Prometheus' patents. But in 2004 Mayo announced that it intended to sell and market its own, somewhat different, diagnostic test. Prometheus sued Mayo contending that Mayo's test infringed its patents. The District Court found that the test infringed the patents but granted summary judgment to Mayo, reasoning that the processes claimed by the patents effectively claim natural laws or natural phenomena—namely, the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drugs—and therefore are not patentable. The Federal Circuit reversed, finding the processes to be patent eligible under the Circuit's "machine or transformation test." On remand from this Court for reconsideration in light of *Bilski* v. *Kappos*, 561 U. S. ___, which clarified that the "machine or transformation test" is not a definitive test of patent eligibility, *id.,* at ___–___, the Federal Circuit reaffirmed its earlier conclusion.

Held: Prometheus' process is not patent eligible. Pp. 8–24.

(a) Because the laws of nature recited by Prometheus' patent claims—the relationships between concentrations of certain metabolites in the blood and the likelihood that a thiopurine drug dosage will prove ineffective or cause harm—are not themselves patentable, the claimed processes are not patentable unless they have additional features that provide practical assurance that the processes are genuine applications of those laws rather than drafting efforts designed to monopolize the correlations. The three additional steps in the claimed processes here are not themselves natural laws but neither are they sufficient to transform the nature of the claims. The "administering" step simply identifies a group of people who will be interested in the correlations, namely, doctors who used thiopurine drugs to treat patients suffering from autoimmune disorders. Doctors had been using these drugs for this purpose long before these patents existed. And a "prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.' " *Bilski*, *supra,* at ___. The "wherein" clauses simply tell a doctor about the relevant natural laws, adding, at most, a suggestion that they should consider the test results when making their treatment decisions. The "determining" step tells a doctor to measure patients' metabolite levels, through whatever process the doctor wishes to use. Because methods for making such determinations were well known in the art, this step simply tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists in the field. Such

activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law. *Parker* v. *Flook*, 437 U. S. 584, 590. Finally, considering the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. Pp. 8–11.

(b) A more detailed consideration of the controlling precedents reinforces this conclusion. Pp. 11–19.

(1) *Diehr* and *Flook,* the cases most directly on point, both addressed processes using mathematical formulas that, like laws of nature, are not themselves patentable. In *Diehr,* the overall process was patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole. 450 U. S., at 187. These additional steps transformed the process into an inventive application of the formula. But in *Flook,* the additional steps of the process did not limit the claim to a particular application, and the particular chemical processes at issue were all "well known," to the point where, putting the formula to the side, there was no "inventive concept" in the claimed application of the formula. 437 U. S., at 594. Here, the claim presents a case for patentability that is weaker than *Diehr*'s patent-eligible claim and no stronger than *Flook*'s unpatentable one. The three steps add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field. Pp. 11–13.

(2) Further support for the view that simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable is provided in *O'Reilly* v. *Morse*, 15 How. 62, 114–115; *Neilson* v. *Harford,* Webster's Patent Cases 295, 371; *Bilski, supra,* at ___–___; and *Benson*, *supra,* at 64, 65, 67. Pp. 14–16.

(3) This Court has repeatedly emphasized a concern that patent law not inhibit future discovery by improperly tying up the use of laws of nature and the like. See, *e.g., Benson,* 409 U. S., at 67, 68. Rewarding with patents those who discover laws of nature might encourage their discovery. But because those laws and principles are "the basic tools of scientific and technological work," *id.,* at 67, there is a danger that granting patents that tie up their use will inhibit future innovation, a danger that becomes acute when a patented process is no more than a general instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify. The patent claims at issue implicate this concern. In telling a doctor to measure metabolite levels and to consider the resulting measurements in light of the correlations they describe, they tie up his subsequent treatment decision re-

gardless of whether he changes his dosage in the light of the inference he draws using the correlations. And they threaten to inhibit the development of more refined treatment recommendations that combine Prometheus' correlations with later discoveries. This reinforces the conclusion that the processes at issue are not patent eligible, while eliminating any temptation to depart from case law precedent. Pp. 16–19.

(c) Additional arguments supporting Prometheus' position—that the process is patent eligible because it passes the "machine or transformation test"; that, because the particular laws of nature that the claims embody are narrow and specific, the patents should be upheld; that the Court should not invalidate these patents under §101 because the Patent Act's other validity requirements will screen out overly broad patents; and that a principle of law denying patent coverage here will discourage investment in discoveries of new diagnostic laws of nature—do not lead to a different conclusion. Pp. 19–24.

628 F. 3d 1347, reversed.

BREYER, J., delivered the opinion for a unanimous Court.

SUPREME COURT OF THE UNITED STATES

No. 10–1150

MAYO COLLABORATIVE SERVICES, DBA MAYO MEDICAL LABORATORIES, ET AL., PETITIONERS *v.* PROMETHEUS LABORATORIES, INC.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[March 20, 2012]

JUSTICE BREYER delivered the opinion of the Court.

Section 101 of the Patent Act defines patentable subject matter. It says:

> "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." 35 U. S. C. §101.

The Court has long held that this provision contains an important implicit exception. "[L]aws of nature, natural phenomena, and abstract ideas" are not patentable. *Diamond* v. *Diehr*, 450 U. S. 175, 185 (1981); see also *Bilski* v. *Kappos*, 561 U. S. ___, ___ (2010) (slip op., at 5); *Diamond* v. *Chakrabarty*, 447 U. S. 303, 309 (1980); *Le Roy* v. *Tatham*, 14 How. 156, 175 (1853); *O'Reilly* v. *Morse*, 15 How. 62, 112–120 (1854); cf. *Neilson* v. *Harford*, Webster's Patent Cases 295, 371 (1841) (English case discussing same). Thus, the Court has written that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could

not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'" *Chakrabarty*, *supra*, at 309 (quoting *Funk Brothers Seed Co.* v. *Kalo Inoculant Co.*, 333 U. S. 127, 130 (1948)).

"Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Gottschalk* v. *Benson*, 409 U. S. 63, 67 (1972). And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.

The Court has recognized, however, that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. Thus, in *Diehr* the Court pointed out that "'a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.'" 450 U. S., at 187 (quoting *Parker* v. *Flook*, 437 U. S. 584, 590 (1978)). It added that "an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Diehr*, *supra,* at 187. And it emphasized Justice Stone's similar observation in *Mackay Radio & Telegraph Co.* v. *Radio Corp. of America,* 306 U. S. 86 (1939):

> "'While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.'" 450 U. S., at 188 (quoting *Mackay Radio*, *supra*, at 94).

See also *Funk Brothers*, *supra*, at 130 ("If there is to be invention from [a discovery of a law of nature], it must come from the application of the law of nature to a new

and useful end").

Still, as the Court has also made clear, to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words "apply it." See, *e.g.*, *Benson*, *supra*, at 71–72.

The case before us lies at the intersection of these basic principles. It concerns patent claims covering processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high. The claims purport to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects. We must determine whether the claimed processes have transformed these unpatentable natural laws into patent-eligible applications of those laws. We conclude that they have not done so and that therefore the processes are not patentable.

Our conclusion rests upon an examination of the particular claims before us in light of the Court's precedents. Those cases warn us against interpreting patent statutes in ways that make patent eligibility "depend simply on the draftsman's art" without reference to the "principles underlying the prohibition against patents for [natural laws]." *Flook*, *supra*, at 593. They warn us against upholding patents that claim processes that too broadly preempt the use of a natural law. *Morse*, *supra*, at 112–120; *Benson*, *supra*, at 71–72. And they insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself. *Flook*, *supra*, at 594; see also *Bilski*, *supra*, at ___ (slip op.,

at 14) ("[T]he prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant postsolution activity'" (quoting *Diehr*, *supra*, at 191–192)).

We find that the process claims at issue here do not satisfy these conditions. In particular, the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field. At the same time, upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.

I

A

The patents before us concern the use of thiopurine drugs in the treatment of autoimmune diseases, such as Crohn's disease and ulcerative colitis. When a patient ingests a thiopurine compound, his body metabolizes the drug, causing metabolites to form in his bloodstream. Because the way in which people metabolize thiopurine compounds varies, the same dose of a thiopurine drug affects different people differently, and it has been difficult for doctors to determine whether for a particular patient a given dose is too high, risking harmful side effects, or too low, and so likely ineffective.

At the time the discoveries embodied in the patents were made, scientists already understood that the levels in a patient's blood of certain metabolites, including, in particular, 6-thioguanine and its nucleotides (6–TG) and 6-methyl-mercaptopurine (6–MMP), were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective. See U. S. Patent No. 6,355,623, col. 8, ll. 37–40, 2 App. 10. ("Previ-

ous studies suggested that measurement of 6–MP metabolite levels can be used to predict clinical efficacy and tolerance to azathioprine or 6–MP" (citing Cuffari, Théorêt, Latour, & Seidman, 6-Mercaptopurine Metabolism in Crohn's Disease: Correlation with Efficacy and Toxicity, 39 Gut 401 (1996))). But those in the field did not know the precise correlations between metabolite levels and likely harm or ineffectiveness. The patent claims at issue here set forth processes embodying researchers' findings that identified these correlations with some precision.

More specifically, the patents—U. S. Patent No. 6,355,623 ('623 patent) and U. S. Patent No. 6,680,302 ('302 patent)—embody findings that concentrations in a patient's blood of 6–TG or of 6–MMP metabolite beyond a certain level (400 and 7000 picomoles per $8x10^8$ red blood cells, respectively) indicate that the dosage is likely too high for the patient, while concentrations in the blood of 6–TG metabolite lower than a certain level (about 230 picomoles per $8x10^8$ red blood cells) indicate that the dosage is likely too low to be effective.

The patent claims seek to embody this research in a set of processes. Like the Federal Circuit we take as typical claim 1 of the '623 Patent, which describes one of the claimed processes as follows:

> "A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
> "(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
> "(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
> "wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to

> increase the amount of said drug subsequently administered to said subject and
> "wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject." '623 patent, col. 20, ll. 10–20, 2 App. 16.

For present purposes we may assume that the other claims in the patents do not differ significantly from claim 1.

B

Respondent, Prometheus Laboratories, Inc. (Prometheus), is the sole and exclusive licensee of the '623 and '302 patents. It sells diagnostic tests that embody the processes the patents describe. For some time petitioners, Mayo Clinic Rochester and Mayo Collaborative Services (collectively Mayo), bought and used those tests. But in 2004 Mayo announced that it intended to begin using and selling its own test—a test using somewhat higher metabolite levels to determine toxicity (450 pmol per $8x10^8$ for 6–TG and 5700 pmol per $8x10^8$ for 6–MMP). Prometheus then brought this action claiming patent infringement.

The District Court found that Mayo's test infringed claim 7 of the '623 patent. App. to Pet. for Cert. 110a–115a. In interpreting the claim, the court accepted Prometheus' view that the toxicity-risk level numbers in Mayo's test and the claim were too similar to render the tests significantly different. The number Mayo used (450) was too close to the number the claim used (400) to matter given appropriate margins of error. *Id.,* at 98a–107a. The District Court also accepted Prometheus' view that a doctor using Mayo's test could violate the patent even if he did not actually alter his treatment decision in the light of the test. In doing so, the court construed the claim's language, "indicates a need to decrease" (or "to increase"), as

not limited to instances in which the doctor actually decreases (or increases) the dosage level where the test results suggest that such an adjustment is advisable. *Id.,* at 107a–109a; see also Brief for Respondent i (describing claimed processes as methods "for improving . . . treatment . . . by using individualized metabolite measurements *to inform* the calibration of . . . dosages of . . . thiopurines" (emphasis added)).

Nonetheless the District Court ultimately granted summary judgment in Mayo's favor. The court reasoned that the patents effectively claim natural laws or natural phenomena—namely the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages—and so are not patentable. App. to Pet. for Cert. 50a–83a.

On appeal, the Federal Circuit reversed. It pointed out that in addition to these natural correlations, the claimed processes specify the steps of (1) "administering a [thiopurine] drug" to a patient and (2) "determining the [resulting metabolite] level." These steps, it explained, involve the transformation of the human body or of blood taken from the body. Thus, the patents satisfied the Circuit's "machine or transformation test," which the court thought sufficient to "confine the patent monopoly within rather definite bounds," thereby bringing the claims into compliance with §101. 581 F. 3d 1336, 1345, 1346–1347 (2009) (internal quotation marks omitted).

Mayo filed a petition for certiorari. We granted the petition, vacated the judgment, and remanded the case for reconsideration in light of *Bilski*, 561 U. S. ___, which clarified that the "machine or transformation test" is not a definitive test of patent eligibility, but only an important and useful clue. *Id.,* at ___–___ (slip op., at 7–8). On remand the Federal Circuit reaffirmed its earlier conclusion. It thought that the "machine-or-transformation test," understood merely as an important and useful clue,

nonetheless led to the "clear and compelling conclusion . . . that the . . . claims . . . do not encompass laws of nature or preempt natural correlations." 628 F. 3d 1347, 1355 (2010). Mayo again filed a petition for certiorari, which we granted.

II

Prometheus' patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. Claim 1, for example, states that *if* the levels of 6–TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per $8x10^8$ red blood cells, *then* the administered dose is likely to produce toxic side effects. While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws? We believe that the answer to this question is no.

A

If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to

monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction "apply the law." Einstein, we assume, could not have patented his famous law by claiming a process consisting of simply telling linear accelerator operators to refer to the law to determine how much energy an amount of mass has produced (or vice versa). Nor could Archimedes have secured a patent for his famous principle of flotation by claiming a process consisting of simply telling boat builders to refer to that principle in order to determine whether an object will float.

What else is there in the claims before us? The process that each claim recites tells doctors interested in the subject about the correlations that the researchers discovered. In doing so, it recites an "administering" step, a "determining" step, and a "wherein" step. These additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim.

First, the "administering" step simply refers 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. In any event, the "prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.'" *Bilski*, *supra,* at ___ (slip op., at 14) (quoting *Diehr*, 450 U. S., at 191–192).

Second, the "wherein" clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient. That is to say, these clauses tell the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decisionmaking (rather like Einstein telling linear accelerator

operators about his basic law and then trusting them to use it where relevant).

Third, the "determining" step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use. As the patents state, methods for determining metabolite levels were well known in the art. '623 patent, col. 9, ll. 12–65, 2 App. 11. Indeed, scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds. '623 patent, col. 8, ll. 37–40, *id.,* at 10. Thus, this step tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field. Purely "conventional or obvious" "[pre]-solution activity" is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law. *Flook*, 437 U. S., at 590; see also *Bilski*, 561 U. S., at ___ (slip op., at 14) ("[T]he prohibition against patenting abstract ideas 'cannot be circumvented by' . . . adding 'insignificant post-solution activity'" (quoting *Diehr*, *supra*, at 191–192)).

Fourth, to consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. See *Diehr*, *supra*, at 188 ("[A] new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made"). Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.

The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in

light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

B

1

A more detailed consideration of the controlling precedents reinforces our conclusion. The cases most directly on point are *Diehr* and *Flook,* two cases in which the Court reached opposite conclusions about the patent eligibility of processes that embodied the equivalent of natural laws. The *Diehr* process (held patent eligible) set forth a method for molding raw, uncured rubber into various cured, molded products. The process used a known mathematical equation, the Arrhenius equation, to determine when (depending upon the temperature inside the mold, the time the rubber had been in the mold, and the thickness of the rubber) to open the press. It consisted in effect of the steps of: (1) continuously monitoring the temperature on the inside of the mold, (2) feeding the resulting numbers into a computer, which would use the Arrhenius equation to continuously recalculate the mold-opening time, and (3) configuring the computer so that at the appropriate moment it would signal "a device" to open the press. *Diehr*, 450 U. S., at 177–179.

The Court pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it found the overall process patent eligible because of the way the additional steps of the process integrated the

equation into the process as a whole. Those steps included "installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time." *Id.,* at 187. It nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional. And so the patentees did not "seek to pre-empt the use of [the] equation," but sought "only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process." *Ibid.* These other steps apparently added to the formula something that in terms of patent law's objectives had significance—they transformed the process into an inventive application of the formula.

The process in *Flook* (held not patentable) provided a method for adjusting "alarm limits" in the catalytic conversion of hydrocarbons. Certain operating conditions (such as temperature, pressure, and flow rates), which are continuously monitored during the conversion process, signal inefficiency or danger when they exceed certain "alarm limits." The claimed process amounted to an improved system for updating those alarm limits through the steps of: (1) measuring the current level of the variable, *e.g.,* the temperature; (2) using an apparently novel mathematical algorithm to calculate the current alarm limits; and (3) adjusting the system to reflect the new alarm-limit values. 437 U. S., at 585–587.

The Court, as in *Diehr,* pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it characterized the claimed process as doing nothing other than "provid[ing] a[n unpatentable] formula for computing an updated alarm limit." *Flook*, *supra*, at 586. Unlike the process in *Diehr*, it did not "explain how the variables used in the formula were to be selected, nor

did the [claim] contain any disclosure relating to chemical processes at work or the means of setting off an alarm or adjusting the alarm limit." *Diehr*, *supra*, at 192, n. 14; see also *Flook*, 437 U. S., at 586. And so the other steps in the process did not limit the claim to a particular application. Moreover, "[t]he chemical processes involved in catalytic conversion of hydrocarbons[,] . . . the practice of monitoring the chemical process variables, the use of alarm limits to trigger alarms, the notion that alarm limit values must be recomputed and readjusted, and the use of computers for 'automatic monitoring-alarming'" were all "well known," to the point where, putting the formula to the side, there was no "inventive concept" in the claimed application of the formula. *Id.,* at 594. "[P]ost-solution activity" that is purely "conventional or obvious," the Court wrote, "can[not] transform an unpatentable principle into a patentable process." *Id.,* at 589, 590.

The claim before us presents a case for patentability that is weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*. Beyond picking out the relevant audience, namely those who administer doses of thiopurine drugs, the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law. These instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field. And since they are steps that must be taken in order to apply the laws in question, the effect is simply to tell doctors to apply the law somehow when treating their patients. The process in *Diehr* was not so characterized; that in *Flook* was characterized in roughly this way.

2

Other cases offer further support for the view that simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable. This Court has previously discussed in detail an English case, *Neilson,* which involved a patent claim that posed a legal problem very similar to the problem now before us. The patent applicant there asserted a claim

> "for the improved application of air to produce heat in fires, forges, and furnaces, where a blowing apparatus is required. [The invention] was to be applied as follows: The blast or current of air produced by the blowing apparatus was to be passed from it into an air-vessel or receptacle made sufficiently strong to endure the blast; and through or from that vessel or receptacle by means of a tube, pipe, or aperture into the fire, the receptacle be kept artificially heated to a considerable temperature by heat externally applied." *Morse*, 15 How., at 114–115.

The English court concluded that the claimed process did more than simply instruct users to use the principle that hot air promotes ignition better than cold air, since it explained how the principle could be implemented in an inventive way. Baron Parke wrote (for the court):

> "It is very difficult to distinguish [Neilson's claim] from the specification of a patent for a principle, and this at first created in the minds of some of the court much difficulty; but after full consideration, we think that the plaintiff does not merely claim a principle, but a machine embodying a principle, and a very valuable one. We think the case must be considered as if the principle being well known, the plaintiff had first

> invented a mode of applying it by a mechanical apparatus to furnaces; and his invention then consists in this—by interposing a receptacle for heated air between the blowing apparatus and the furnace. In this receptacle he directs the air to be heated by the application of heat externally to the receptacle, and thus he accomplishes the object of applying the blast, which was before of cold air, in a heated state to the furnace." *Neilson* v. *Harford*, Webster's Patent Cases, at 371.

Thus, the claimed process included not only a law of nature but also several unconventional steps (such as inserting the receptacle, applying heat to the receptacle externally, and blowing the air into the furnace) that confined the claims to a particular, useful application of the principle.

In *Bilski* the Court considered claims covering a process for hedging risks of price changes by, for example, contracting to purchase commodities from sellers at a fixed price, reflecting the desire of sellers to hedge against a drop in prices, while selling commodities to consumers at a fixed price, reflecting the desire of consumers to hedge against a price increase. One claim described the process; another reduced the process to a mathematical formula. 561 U. S., at ___–___ (slip op., at 2–3). The Court held that the described "concept of hedging" was "an unpatentable abstract idea." *Id.,* at ___ (slip op., at 15). The fact that some of the claims limited hedging to use in commodities and energy markets and specified that "well-known random analysis techniques [could be used] to help establish some of the inputs into the equation" did not undermine this conclusion, for "*Flook* established that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable." *Id.,* at ___, ___ (slip op., at 16, 15).

Finally, in *Benson* the Court considered the patentability of a mathematical process for converting binary-coded decimal numerals into pure binary numbers on a general purpose digital computer. The claims "purported to cover any use of the claimed method in a general-purpose digital computer of any type." 409 U. S., at 64, 65. The Court recognized that "'a novel and useful structure created with the aid of knowledge of scientific truth'" might be patentable. *Id.,* at 67 (quoting *Mackay Radio*, 306 U. S., at 94). But it held that simply implementing a mathematical principle on a physical machine, namely a computer, was not a patentable application of that principle. For the mathematical formula had "no substantial practical application except in connection with a digital computer." *Benson*, *supra*, at 71. Hence the claim (like the claims before us) was overly broad; it did not differ significantly from a claim that just said "apply the algorithm."

3

The Court has repeatedly emphasized this last mentioned concern, a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature. Thus, in *Morse* the Court set aside as unpatentable Samuel Morse's general claim for "'the use of the motive power of the electric or galvanic current . . . however developed, for making or printing intelligible characters, letters, or signs, at any distances,'" 15 How., at 86. The Court explained:

> "For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by

> this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee." *Id.*, at 113.

Similarly, in *Benson* the Court said that the claims before it were "so abstract and sweeping as to cover both known and unknown uses of the [mathematical formula]." 409 U. S., at 67, 68. In *Bilski* the Court pointed out that to allow "petitioners to patent risk hedging would preempt use of this approach in all fields." 561 U. S., at ___ (slip op., at 15). And in *Flook* the Court expressed concern that the claimed process was simply "a formula for computing an updated alarm limit," which might "cover a broad range of potential uses." 437 U. S., at 586.

These statements reflect the fact that, even though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are "the basic tools of scientific and technological work." *Benson*, *supra*, at 67. And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify. See generally Lemley, Risch, Sichelman, & Wagner, Life After *Bilski,* 63 Stan. L. Rev. 1315 (2011) (hereinafter Lemley) (arguing that §101 reflects this kind of concern); see also C. Bohannan & H. Hovenkamp, Creation without Restraint: Promoting Liberty and Rivalry in Innovation 112 (2012) ("One problem with [process] patents is that the more abstractly their claims are stated, the more difficult it is to determine precisely what they cover. They risk being applied to a wide range of situations that were not anticipated by the patentee"); W. Landes & R. Posner, The Economic Struc-

ture of Intellectual Property Law 305–306 (2003) (The exclusion from patent law of basic truths reflects "both . . . the enormous potential for rent seeking that would be created if property rights could be obtained in them and . . . the enormous transaction costs that would be imposed on would-be users [of those truths]").

The laws of nature at issue here are narrow laws that may have limited applications, but the patent claims that embody them nonetheless implicate this concern. They tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe. In doing so, they tie up the doctor's subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations. And they threaten to inhibit the development of more refined treatment recommendations (like that embodied in Mayo's test), that combine Prometheus' correlations with later discovered features of metabolites, human physiology or individual patient characteristics. The "determining" step too is set forth in highly general language covering all processes that make use of the correlations after measuring metabolites, including later discovered processes that measure metabolite levels in new ways.

We need not, and do not, now decide whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them. For here, as we have said, the steps add nothing of significance to the natural laws themselves. Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws. The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible, while eliminating any temptation

to depart from case law precedent.

III

We have considered several further arguments in support of Prometheus' position. But they do not lead us to adopt a different conclusion. First, the Federal Circuit, in upholding the patent eligibility of the claims before us, relied on this Court's determination that "[t]ransformation and reduction of an article 'to a different state or thing' is *the clue* to the patentability of a process claim that does not include particular machines." *Benson*, *supra*, at 70–71 (emphasis added); see also *Bilski*, *supra*, at ___ (slip op., at 6–7); *Diehr*, 450 U. S., at 184; *Flook*, *supra*, at 588, n. 9; *Cochrane* v. *Deener*, 94 U. S. 780, 788 (1877). It reasoned that the claimed processes are therefore patent eligible, since they involve transforming the human body by administering a thiopurine drug and transforming the blood by analyzing it to determine metabolite levels. 628 F. 3d, at 1356–1357.

The first of these transformations, however, is irrelevant. As we have pointed out, the "administering" step simply helps to pick out the group of individuals who are likely interested in applying the law of nature. See *supra,* at 9. And the second step could be satisfied without transforming the blood, should science develop a totally different system for determining metabolite levels that did not involve such a transformation. See *supra,* at 18. Regardless, in stating that the "machine-or-transformation" test is an "*important and useful clue"* to patentability, we have neither said nor implied that the test trumps the "law of nature" exclusion. *Bilski*, *supra*, at ___ (slip op., at 6–7) (emphasis added). That being so, the test fails here.

Second, Prometheus argues that, because the particular laws of nature that its patent claims embody are narrow and specific, the patents should be upheld. Thus, it encourages us to draw distinctions among laws of nature

based on whether or not they will interfere significantly with innovation in other fields now or in the future. Brief for Respondent 42–46; see also Lemley 1342–1344 (making similar argument).

But the underlying functional concern here is a *relative* one: how much future innovation is foreclosed relative to the contribution of the inventor. See *supra,* at 17. A patent upon a narrow law of nature may not inhibit future research as seriously as would a patent upon Einstein's law of relativity, but the creative value of the discovery is also considerably smaller. And, as we have previously pointed out, even a narrow law of nature (such as the one before us) can inhibit future research. See s*upra*, at 17–18.

In any event, our cases have not distinguished among different laws of nature according to whether or not the principles they embody are sufficiently narrow. See, *e.g., Flook*, 437 U. S. 584 (holding narrow mathematical formula unpatentable). And this is understandable. Courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature. And so the cases have endorsed a bright-line prohibition against patenting laws of nature, mathematical formulas and the like, which serves as a somewhat more easily administered proxy for the underlying "building-block" concern.

Third, the Government argues that virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy §101's demands. Brief for United States as *Amicus Curiae.* The Government does not necessarily believe that claims that (like the claims before us) extend just minimally beyond a law of nature should receive patents. But in its view, other statutory provisions—those that insist that a claimed process be novel, 35 U. S. C. §102, that it not be

"obvious in light of prior art," §103, and that it be "full[y], clear[ly], concise[ly], and exact[ly]" described, §112—can perform this screening function. In particular, it argues that these claims likely fail for lack of novelty under §102.

This approach, however, would make the "law of nature" exception to §101 patentability a dead letter. The approach is therefore not consistent with prior law. The relevant cases rest their holdings upon section 101, not later sections. *Bilski*, 561 U. S. ___; *Diehr*, *supra*; *Flook*, *supra*; *Benson*, 409 U. S. 63. See also H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952) ("A person may have 'invented' a machine or a manufacture, which may include anything under the sun that is made by man, *but it is not necessarily patentable under section 101* unless the conditions of the title are fulfilled" (emphasis added)).

We recognize that, in evaluating the significance of additional steps, the §101 patent-eligibility inquiry and, say, the §102 novelty inquiry might sometimes overlap. But that need not always be so. And to shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.

What role would laws of nature, including newly discovered (and "novel") laws of nature, play in the Government's suggested "novelty" inquiry? Intuitively, one would suppose that a newly discovered law of nature is novel. The Government, however, suggests in effect that the novelty of a component law of nature may be disregarded when evaluating the novelty of the whole. See Brief for United States as *Amicus Curiae* 27. But §§102 and 103 say nothing about treating laws of nature as if they were part of the prior art when applying those sections. Cf. *Diehr,* 450 U. S., at 188 (patent claims "must be considered as a whole"). And studiously ignoring *all* laws of nature when evaluating a patent application under §§102

and 103 would "make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious." *Id.*, at 189, n. 12. See also Eisenberg, Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After *In re Bilski,* 3 Case W. Res. J. L. Tech. & Internet 1, ___ (forthcoming, 2012) (manuscript, at 85–86, online at http://www.patentlyo.com/files/eisenberg.wisdomordeadhand.patentlyo.pdf (as visited Mar. 16, 2012, and available in Clerk of Court's case file)); 2 D. Chisum, Patents §5.03[3] (2005).

Section 112 requires only a "written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." It does not focus on the possibility that a law of nature (or its equivalent) that meets these conditions will nonetheless create the kind of risk that underlies the law of nature exception, namely the risk that a patent on the law would significantly impede future innovation. See Lemley 1329–1332 (outlining differences between §§101 and 112); Eisenberg, *supra,* at ___ (manuscript, at 92–96) (similar). Compare Risch, Everything is Patentable, 75 Tenn. L. Rev. 591 (2008) (defending a minimalist approach to §101) with Lemley (reflecting Risch's change of mind).

These considerations lead us to decline the Government's invitation to substitute §§102, 103, and 112 inquiries for the better established inquiry under §101.

Fourth, Prometheus, supported by several *amici,* argues that a principle of law denying patent coverage here will interfere significantly with the ability of medical researchers to make valuable discoveries, particularly in the area of diagnostic research. That research, which includes research leading to the discovery of laws of nature, is expensive; it "ha[s] made the United States the world leader in this field"; and it requires protection. Brief for

Respondent 52.

Other medical experts, however, argue strongly against a legal rule that would make the present claims patent eligible, invoking policy considerations that point in the opposite direction. The American Medical Association, the American College of Medical Genetics, the American Hospital Association, the American Society of Human Genetics, the Association of American Medical Colleges, the Association for Molecular Pathology, and other medical organizations tell us that if "claims to exclusive rights over the body's natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care." Brief for American College of Medical Genetics et al. as *Amici Curiae* 7; see also App. to Brief for Association Internationale pour la Protection de la Propriété Intellectuelle et al. as *Amici Curiae* A6, A16 (methods of medical treatment are not patentable in most of Western Europe).

We do not find this kind of difference of opinion surprising. Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements. At the same time, patent law's general rules must govern inventive activity in many different fields of human endeavor, with the result that the practical effects of rules that reflect a general effort to balance these considerations may differ from one field to another. See Bohannan &

Hovenkamp, Creation without Restraint, at 98–100.

In consequence, we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary. Cf. 35 U. S. C. §§161–164 (special rules for plant patents). We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable.

* * *

For these reasons, we conclude that the patent claims at issue here effectively claim the underlying laws of nature themselves. The claims are consequently invalid. And the Federal Circuit's judgment is reversed.

It is so ordered.

BAKER DONELSON
BEARMAN, CALDWELL & BERKOWITZ, PC

The Meaning of "Disclosure"

Shazi Jiang, M.D., J.D.

EXPAND YOUR EXPECTATIONS™

35 U.S.C. § 102 (Newly Amended by AIA)

Sec. 102. Conditions for patentability; novelty

A person 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*** before the effective filing date of the claimed invention…EXCEPT [a] ***disclosure*** made 1 year or less before the effective filing date of a claimed invention shall not be prior art…if-

- A. the ***disclosure*** was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
- B. the subject matter disclosed had, before such disclosure, been ***publicly disclosed*** by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

Can an Inventor's "Disclosure" include every type of prior art listed in new Section 102(a)(1)?

Is a public use, sale, or offer for sale a "disclosure" that can be excluded from prior art under the modified grace period?

Canons of Statutory Interpretation

- Textual Canons:
  - Linguistic inference:
    - Plain Meaning
    - *Ejusdem generis*
    - *Expressio unius est exclusio alterius*
    - *In pari materia*
    - *Noscitur a sociis*
    - *Reddengo singula singulis*
    - *Generalia specialibus non derogant*
    - Ordinary Usage
    - Dictionary definition
  - Textual Integrity: (Context)
    - Whole Act Rule
    - Presumption of consistent usage/ meaningful variation
    - Avoid inconsistent policy
    - Avoid inconsistent assumption
    - Avoid inconsistent structure
    - Rule against surplusage
    - Specific/General
    - narrow exceptions
    - No exceptions created
- Extrinsic Source Canons
  - Agency interpretation
  - Continuity in law
    - Rule of Continuity
    - Consistency between statutes
    - Reenactment Rules
    - Acquiescence Rule
    - Obsolete reason, obsolete rule
    - same reason, same rule
    - Borrowed statute rule
  - Extrinsic Legislative Sources
    - Legislative history
    - Committee Reports
    - legislative intent
    - The "dog didn't bark" cannon
- Substantive Canons:
  - Avoidance/ unconstitutionality
  - Interpretation in Light of Fundamental Values
  - Rule of Lenity
  - Avoidance of abrogation of state sovereignty
  - Purpose/ Object Rule
  - Common Law Usage
  - Liberal Construction

Plain Meaning Canon: Is "disclosure" clear?

- "As in all statutory construction cases, we begin with the language of the statute. The first step is to determine whether the language at issue has a plain and unambiguous meaning..." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002).
- "Unless otherwise defined, statutory words will be interpreted as taking their ordinary, contemporary common meaning." *United States v. Piervinanzi*, 23 F.3d 670, 677 (2d Cir. 1994).

- Dictionary meaning of "disclosure":
  - Disclosure includes the act of disclosing, which is to "make known or public." (Merriam-Webster Dictionary).
  - So, this might not apply to certain public uses, sales, or offers for sale of the invention.

Common Law Usage

- Federal Circuit has held that a "disclosure" of the invention would require that the disclosed material be "enabling," that it teach those skilled in the art how to make and use the full scope of claimed invention without "undue experimentation."
  - *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005) (holding that a "disclosure is prior art to the extent of its enabling disclosure")
  - *In re Donohue*, 766 F.2d 351 (Fed. Cir. 1985) ("Even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling")

Common Law Usage

The Federal Circuit has also held that "non-informing" uses or sales of the claimed invention that are not enabling may count as prior art under the current statute (if occurring more than 1 year before filing)

- *In re Epstein*, 32 F.3d 1559 (Fed. Cir. 1994) ("Beyond this 'in public use or on sale' finding, there is no requirement for an enablement-type inquiry.")
- *J. A. LaPorte Inc. v. Norfolk Dredging Company*, 787 F.2d 1577 (Fed. Cir. 1986) ("Our precedent holds that the question is not whether the sale, even a third party sale, 'discloses' the invention at the time of the sale, but whether the sale relates to a device that *embodies* the invention.")
- *Metallizing Engineering Co v. Kenyon*, 153 F.2d 516 (2d Cir. 1946) (Inventor's competitive exploitation of his machine or process for more than a year prior to application for patent operates as a forfeiture of right to patent regardless of how little public may have learned about invention.)

Thus, "disclosure" arguably may not exclude from prior art certain public uses or sales made within the grace period.

Consistency / Differences With Existing Section 102

- Currently under 35 USC 102: A person shall be entitled to a patent unless -
  - (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

Legislative History / legislative intent

- "New section 102(b) preserves the grace period, ensuring that during the year prior to filing, an invention will not be rendered unpatentable based on any of the inventor's own disclosures, or any disclosure made by any party after the inventor has disclosed his invention to the public." (House Cmte Rep. 112-98, p. 73).
- "[Grace period] will apply to all actions by the patent owner during the year prior to filing that would otherwise create 102(a) prior art." (House Cmte Rep. 112-98, p. 43).

Legislative History / legislative intent, Cont.

- Congressional Record S1496 of Senators Leahy and Hatch:
  - "We intend that if an inventor's actions are such as to constitute prior art under subsection 102(a), then those actions necessarily trigger subsection 102(b)'s protections for the inventor and, what would otherwise have been section 102(a) prior art, would be excluded as prior art by the grace period provided by subsection 102(b)."
  - "By a 'public disclosure' I mean one that results in the claimed invention being 'described in a printed publication, or in public use, on sale, or otherwise available to the public.'"
  - "Indeed, as an example of this, subsection 102(b)(1)(A), as written, was deliberately couched in broader terms than subsection 102(a)(1)."
  - "This means that any disclosure by the inventor whatsoever, whether or not in a form that resulted in the disclosure being available to the public, is wholly disregarded as prior art."

Language Variance and Rule against Surplusage

- The statute does distinguish between "disclosure" and "public disclosure"
  - **35 USC 102(b)(1):** DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION- A **disclosure** made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—
    - A. the **disclosure** was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
    - B. the subject matter disclosed had, before such disclosure, been **publicly disclosed** by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.
- Thus, not all disclosures are public disclosures.

Whole Act Rule / Inconsistent Structure (Context)

- Amended 35 USC 102(b)(1):
  - **DISCLOSURES** MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION- A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if…
- The grace period under 102(b)(1) refers to and is an exception to 102(a)(1), and thus, an argument can be made that the generic word "disclosure" refers to all categories of prior art listed in 102(a)(1).

Summary

The Act does not define what constitutes “disclosure” sufficient to trigger the grace period of 102(b).

The meaning of the term will likely be clarified by future litigation and Court interpretation using the Canons of Statutory Interpretation.

Appendix B

THE REHNQUIST COURT'S CANONS OF STATUTORY INTERPRETATION

A study collected the canons used by the Supreme Court in the 1986 through 1993 Terms and divided the canons into three categories that essentially parallel the typology provided in Chapter 8. Below is a listing of these canons, stripped of the footnotes citing the cases in which they are found.[a]

TEXTUAL CANONS

- Plain meaning rule: follow the plain meaning of the statutory text, except when text suggests an absurd result or a scrivener's error.

LINGUISTIC INFERENCES

- *Expressio unius*: expression of one thing suggests the exclusion of others.
- *Noscitur a sociis*: interpret a general term to be similar to more specific terms in a series.
- *Ejusdem generis*: interpret a general term to reflect the class of objects reflected in more specific terms accompanying it.
- Follow ordinary usage of terms, unless Congress gives them a specified or technical meaning.
- Follow dictionary definitions of terms, unless Congress has provided a specific definition. Consider dictionaries of the era in which the statute was enacted. Do not consider "idiosyncratic" dictionary definitions.
- "May" is usually precatory, while "shall" is usually mandatory.
- "Or" means in the alternative.

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a. William Eskridge, Jr. & Philip Frickey, *The Supreme Court, 1993 Term — Foreword: Law as Equilibrium*, 108 Harv. L. Rev. 26, 97-108 (1994).

GRAMMAR AND SYNTAX

- Punctuation rule: Congress is presumed to follow accepted punctuation standards, so that placements of commas and other punctuation are assumed to be meaningful.
- Do not have to apply the "rule of the last antecedent" if not practical.

TEXTUAL INTEGRITY

- Each statutory provision should be read by reference to the whole act. Statutory interpretation is a "holistic" endeavor.
- Avoid interpreting a provision in a way that would render other provisions of the Act superfluous or unnecessary.
- Avoid interpreting a provision in a way inconsistent with the policy of another provision.
- Avoid interpreting a provision in a way that is inconsistent with a necessary assumption of another provision.
- Avoid interpreting a provision in a way that is inconsistent with the structure of the statute.
- Avoid broad readings of statutory provisions if Congress has specifically provided for the broader policy in more specific language elsewhere.
- Interpret the same or similar terms in a statute the same way.
- Specific provisions targeting a particular issue apply instead of provisions more generally covering the issue.
- Provisos and statutory exceptions should be read narrowly.
- Do not create exceptions in addition to those specified by Congress.

EXTRINSIC SOURCE CANONS

AGENCY INTERPRETATIONS

- Rule of deference to agency interpretations, unless contrary to plain meaning of statute or unreasonable.
- Rule of extreme deference when there is express delegation of law-making duties to agency.
- Presumption that agency interpretation of its own regulations is correct.

CONTINUITY IN LAW

- Rule of continuity: assume that Congress does not create discontinuities in legal rights and obligations without some clear statement.
- Presumption that Congress uses same term consistently in different statutes.
- Super-strong presumption of correctness for statutory precedents.
- Presumption that international agreements do not displace federal law.

- Borrowed statute rule: when Congress borrows a statute, it adopts by implication interpretations placed on that statute, absent express statement to the contrary.
- Re-enactment rule: when Congress re-enacts a statute, it incorporates settled interpretations of the re-enacted statute. The rule is inapplicable when there is no settled standard Congress could have known.
- Acquiescence rule: consider unbroken line of lower court decisions interpreting statute, but do not give them decisive weight.

EXTRINSIC LEGISLATIVE SOURCES

- Interpret provision consistent with subsequent statutory amendments, but do not consider subsequent legislative discussions.
- Consider legislative history if the statute is ambiguous.
- Committee reports are authoritative legislative history, but cannot trump a textual plain meaning, and should not be relied on if they are "imprecise."
- Committee report language that cannot be tied to a specific statutory provision cannot be credited. House and Senate reports inconsistent with one another should be discounted.
- Presumption against interpretation considered and rejected by floor vote of a chamber of Congress or committee.
- Floor statements can be used to confirm apparent meaning.
- Contemporaneous and subsequent understandings of a statutory scheme (including understandings by President and Department of Justice) may sometimes be admissible.
- The "dog didn't bark" canon: presumption that prior legal rule should be retained if no one in legislative deliberations even mentioned the rule or discussed any changes in the rule.

SUBSTANTIVE POLICY CANONS

CONSTITUTION-BASED CANONS

- Avoid interpretations that would render a statute unconstitutional. Inapplicable if statute would survive constitutional attack, or if statutory text is clear.

1. Separation of Powers

- Super-strong rule against congressional interference with President's authority over foreign affairs and national security.
- Rule against congressional invasion of the President's core executive powers.
- Rule against review of President's core executive actions for "abuse of discretion."

- Rule against congressional curtailment of the judiciary's "inherent powers" or its "equity" powers.
- Rule against congressional expansion of Article III injury in fact to include intangible and procedural injuries.
- Presumption that Congress does not delegate authority without sufficient guidelines.
- Presumption against "implying" causes of action into federal statutes.
- Presumption that U.S. law conforms to U.S. international obligations.
- Rule against congressional abrogation of Indian treaty rights.
- Presumption favoring severability of unconstitutional provisions.

2. Federalism

- Super-strong rule against federal invasion of "core state functions."
- Super-strong rule against federal abrogation of states' Eleventh Amendment immunity from lawsuits in federal courts.
- Rule against inferring enforceable conditions on federal grants to the states.
- Rule against congressional expansion of federal court jurisdiction that would siphon cases away from state courts.
- Rule against reading a federal statute to authorize states to engage in activities that would violate the dormant commerce clause.
- Rule favoring concurrent state and federal court jurisdiction over federal claims.
- Rule against federal pre-emption of traditional state functions, or against federal disruption of area of traditional state regulation.
- Presumption against federal pre-emption of state-assured family support obligations.
- Presumption against federal regulation of intergovernmental taxation by the states.
- Presumption against application of federal statutes to state and local political processes.
- Presumption that states can tax activities within their borders, including Indian tribal activities, but also presumption that states cannot tax on Indian lands.
- Presumption against congressional derogation from state's land claims based upon its entry into Union on an "equal footing" with all other states.
- Presumption against federal habeas review of state criminal convictions supported by independent state ground.
- Pesumption of finality of state convictions for purposes of habeas review.

- Principle that federal equitable remedies must consider interests of state and local authorities.
- Presumption that Congress borrows state statutes of limitations for federal statutory schemes, unless otherwise provided.

3. Due Process

- Rule of lenity: rule against applying punitive sanctions if there is ambiguity as to underlying criminal liability or criminal penalty.
- Rule of lenity applies to civil sanction that is punitive or when underlying liability is criminal.
- Rule against criminal penalties imposed without showing of specific intent.
- Rule against interpreting statutes to be retroactive, even if statute is curative or restorative.
- Rule against interpreting statutes to deny a right to jury trial.
- Presumption in favor of judicial review, especially for constitutional questions, but not for agency decisions not to prosecute.
- Presumption against pre-enforcement challenges to implementation.
- Presumption against exhaustion of remedies requirement for lawsuit to enforce constitutional rights.
- Presumption that judgments will not be binding upon persons not party to adjudication.
- Presumption against national service of process unless authorized by Congress.
- Presumption against foreclosure of private enforcement of important federal rights.
- Presumption that preponderance of the evidence standard applies in civil cases.

STATUTE-BASED CANONS

- *In pari materia*: similar statutes should be interpreted similarly, unless legislative history or purpose suggests material differences.
- Presumption against repeals by implication.
- Purpose rule: interpret ambiguous statutes so as best to carry out their statutory purposes.
- Narrow interpretation of statutory exemptions.
- Presumption against creating exemptions in a statute that has none.
- Allow *de minimis* exceptions to statutory rules, so long as they do not undermine statutory policy.
- Presumption that federal private right of action (express or implied) carries with it all traditional remedies.

- Presumption that court will not supply a sanction for failure to follow a timing provision when the statute has no sanction.
- Rule against state taxation of Indian tribes and reservation activities.
- Presumption against national "diminishment" of Indian lands.
- Narrow interpretation of exemptions from federal taxation.
- Presumption against taxpayer claiming income tax deduction.
- Presumption that the Bankruptcy Act of 1978 preserved prior bankruptcy doctrines.
- Federal court deference to arbitral awards, even where the Federal Arbitration Act is not by its terms applicable.
- Strong presumption in favor of enforcing labor arbitration agreements.
- Rule favoring arbitration of federal statutory claims.
- Strict construction of statutes authorizing appeals.
- Rule that Court of Claims is proper forum for Tucker Act claims against federal government.
- Rule that "sue and be sued" clauses waive sovereign immunity and should be liberally construed.
- Presumption that statute creating agency and authorizing it to "sue and be sued" also creates federal subject matter jurisdiction for lawsuits by and against the agency.
- Construe ambiguities in deportation statutes in favor of aliens.
- Principle that veterans' benefits statutes be construed liberally for their beneficiaries.
- Liberal application of antitrust policy.
- Presumption against application of Sherman Act to activities authorized by states.
- Principle that statutes should not be interpreted to create anticompetitive effects.
- Strong presumption that federal grand juries operate within legitimate spheres of their authority.

COMMON LAW-BASED CANONS

- Presumption in favor of following common law usage where Congress has employed words or concepts with well settled common law traditions. Follow evolving common law unless inconsistent with statutory purposes.
- Rule against extraterritorial application of U.S. law, except for antitrust laws.
- Super-strong rule against waivers of United States sovereign immunity.
- Rule that debts to the United States shall bear interest.

- Super-strong rule against conveyance of U.S. public lands to private parties.
- Rule presuming against attorney fee-shifting in federal courts and federal statutes, and narrow construction of fee-shifting statutes to exclude unmentioned costs.
- Presumption that jury finds facts, judge declares law.
- Rule presuming that law takes effect on date of enactment.
- Presumption that public (government) interest not be prejudiced by negligence of federal officials.
- Presumption that federal agencies launched into commercial world with power to "sue and be sued" are not entitled to sovereign immunity.
- Presumption favoring enforcement of forum selection clauses.
- Presumption against criminal jurisdiction by an Indian tribe over a nonmember.
- Presumption that party cannot invoke federal jurisdiction until she has exhausted her remedies in Indian tribal courts.
- Presumption that federal judgment has preclusive effect in state administrative proceedings.
- Presumption importing common law immunities into federal civil rights statutes.

Smith-Leahy America Invents Act

Sec. 102. Conditions for patentability; novelty

(a) Novelty; Prior Art- A person shall be entitled to a patent unless—

1. the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

2. the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

(b) Exceptions-

1. DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION- A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if-

A. the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

B. the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

2. DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS- A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if-

A. the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;

B. the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

C. the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

BAKER DONELSON
BEARMAN, CALDWELL & BERKOWITZ, PC

Test Driving the AIA

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(202) 508-3400**

EXPAND YOUR EXPECTATIONS™

Two-Tiered Definition of Prior Art

- 35 USC 102(a): Defines “prior art”
- 35 USC 102(b): Defines “exclusions” from definition of prior art

1. The applicant may no longer rely on an earlier invention date to swear behind art

35 U.S.C. §102(a): Definition of prior art

- Patents, printed publications, public uses, materials that are "on-sale", or anything else "available to the public" before the effective filing date **[35 USC 102(a)(1)]**
- Patents and published applications having an earlier effective filing date **[35 USC 102(a)(2)]**

2. The applicant may rely on an earlier public disclosure to overcome art

Disclosure not prior art if less than one year before the effective filing date **AND**

- Subject matter was obtained directly or indirectly from inventor; or
- Disclosure was made after a "public disclosure" by the inventor, joint inventor, "or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor"

35 USC §102(b)(1)

2. The applicant may rely on an earlier public disclosure to overcome art, cont'd

Prior application is not prior art if:

- Subject matter of application was obtained directly or indirectly from the inventor or joint inventor;

OR

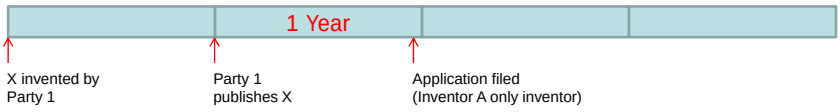
- Before the effective filing date of the prior application, the subject matter was "publically disclosed" by the inventor or a joint inventor or another who obtained the subject matter directly or indirectly from the inventor or a joint inventor

OR

- The 102(a)(2) art and the "claimed invention" were owned by, or subject to an obligation of assignment to, the same person

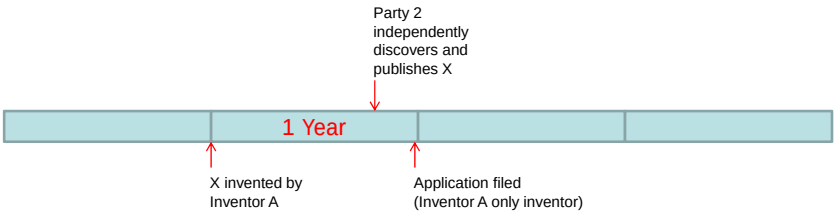
35 USC §102(b)(2)

Scenario 1: Prior publication by inventor



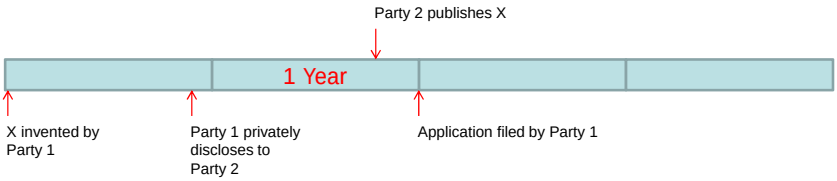
- **Old 102**: **PATENT GRANTS**
- **New 102:** **PATENT GRANTS**
- Inventor A's publication satisfies definition of prior art under 35 U.S.C. 102(a)(1), but falls within exclusion under 35 USC 102(b)(1)

Scenario 2: Prior publication by another



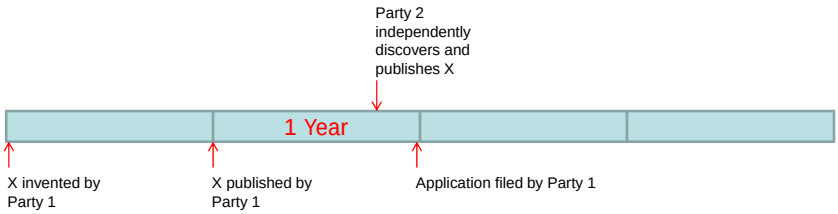
- **Old 102**: **PATENT GRANTS**
- **New 102**: **PATENT DOES NOT GRANT**
- Party 2's publication satisfies definition of prior art under 35 U.S.C. 102(a)(1) and does not fall within exclusion under 35 USC 102(b)

Scenario 3: Prior publication by another



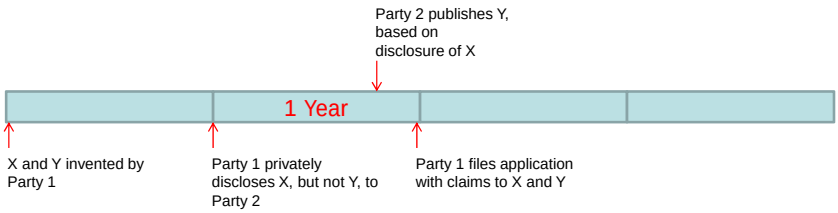
- **Old 102**: PATENT GRANTS
- **New 102**: PATENT GRANTS
- Party 2's publication qualifies as prior art under 35 U.S.C. 102(a)(1), but falls within exclusion under 35 USC 102(b)(1)(A)

Scenario 4: Competing publications



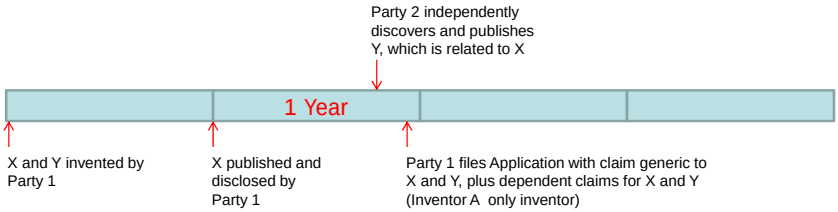
- **Old 102**: PATENT GRANTS
- **New 102**: PATENT GRANTS
- Party 1's publication satisfies 35 USC 102(a)(1), but falls within exception under 35 USC 102(b)(1)
- Party 2's publication satisfies definition of prior art under 35 U.S.C. 102(a)(1), but falls within exclusion under 35 USC 102(b)(2)

Scenario 5: Prior publication by another



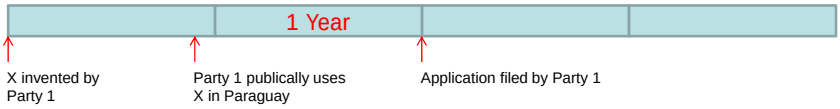
- **Old 102**: PATENT GRANTS FOR ALL CLAIMS
- **New 102**: DISPOSITION OF CLAIMS IS UNCERTAIN
- Party 2's publication qualifies as prior art under 35 U.S.C. 102(a)(1), but does it fall within exclusion under 35 USC 102(b)(1)(A)?
- QUESTION: Did Party 2 obtain Y "directly or indirectly from" Party 1? If not, can Party 2's publication be used against X under 35 USC 103?

Scenario 6: Competing publications



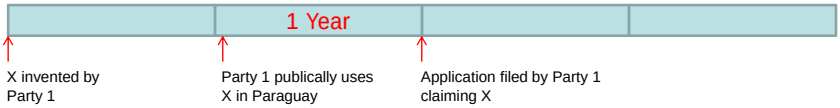
- **Old 102**: PATENT GRANTS FOR ALL CLAIMS
- **New 102**: PATENT GRANTS FOR X, MAYBE NOT FOR GENERIC OR Y
- Party 2's publication may fall within exception under 35 USC 102(b)(1) with respect to X
- Can publication of X by Party 1 be considered a "public disclosure" of generic? What about Y?

Scenario 7: Foreign sale or use



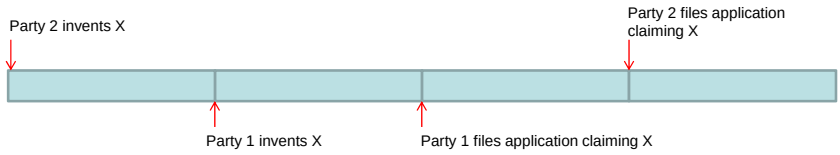
- **Old 102**: **PATENT GRANTS**
- **New 102:** **PATENT DOES NOT GRANT**
- Party 1's use satisfies definition of prior art under 35 U.S.C. 102(a)(1) and does not fall within exclusion under 35 USC 102(b)

Scenario 8: Foreign sale or use



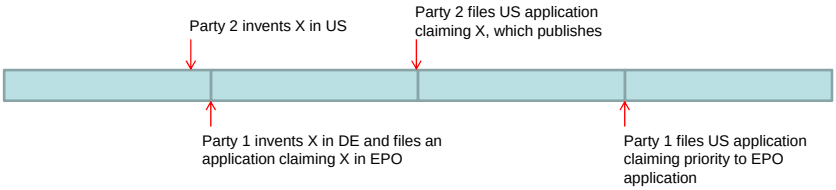
- **Old 102**: **PATENT GRANTS**
- **New 102:** **???**
- Inventor A's use satisfies definition of prior art under 35 U.S.C. 102(a)(1), but does it falls within exclusion under 35 USC 102(b)(1)?

Scenario 9: Earlier Application



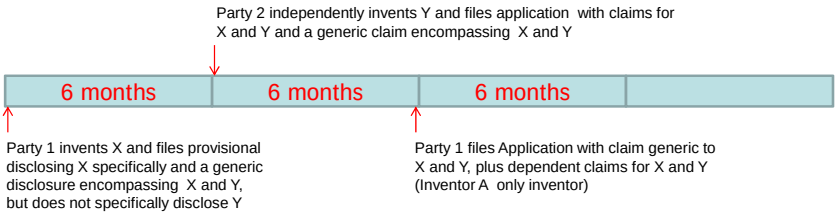
- **Old 102**: PATENT GRANTS TO PARTY 2
- **New 102**: PATENT GRANTS TO PARTY 1
- Party 2's application does not qualify as prior art under 35 U.S.C. 102(a)(1)
- Party 1's application qualifies as prior art under 35 U.S.C. 102(a)(2) and does not fall within exclusion under 35 USC 102(b)

Scenario 10: Earlier Application



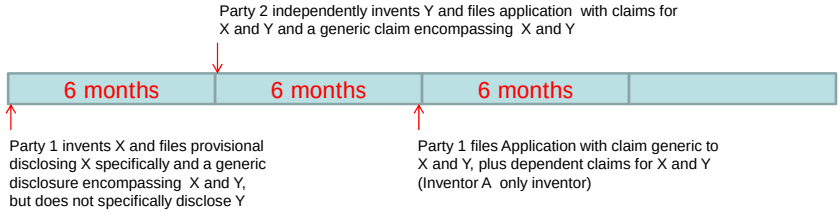
- **Old 102**: PATENT GRANTS TO PARTY 2
- **New 102**: PATENT GRANTS TO PARTY 1
- Party 2's application does not qualify as prior art under 35 U.S.C. 102(a)
- Party 1's application qualifies as prior art under 35 U.S.C. 102(a)(2) and does not fall within exclusion under 35 USC 102(b)

Scenario 11: Intervening application



- **Old 102**: INTERFERENCE FOR ALL CLAIMS
- **New 102**: PATENT GRANTS TO PARTY 1 FOR X and GENERIC; DISPOSITION OF Y IS UNCLEAR
- Party 1's provisional application satisfies 35 USC 102(a)(2) with respect to X and generic and does not fall under 35 USC 102(b)
- Disposition of Y hinges on whether Y is considered "effectively filed" as of Party 1's provisional application

Scenario 11: Intervening application, *cont'd*



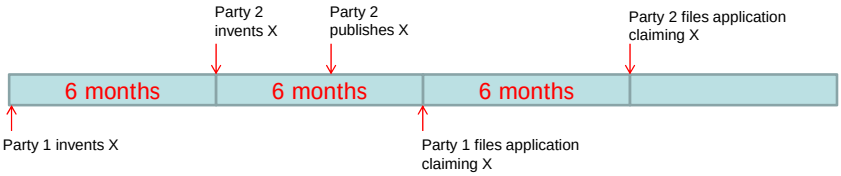
35 USC 102(d)(2)

> [a] patent or application shall be considered to have been effectively filed . . . as of the filing date of the earliest such application that describes the subject matter

QUESTION #1: Does this require compliance with 35 USC 112 or a specific disclosure?

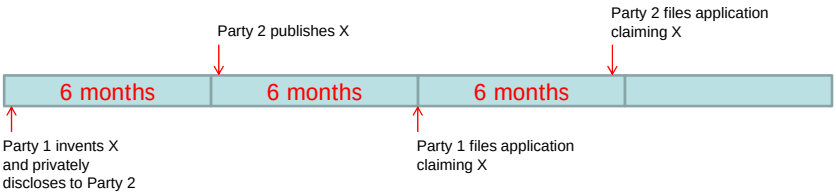
QUESTION #2: Can you think of a scenario where a generic claim is described and enabled, but a species is not?

Scenario 12: Early Application vs. Early Publication



- **Old 102**: PATENT GRANTS TO PARTY 1
- **New 102**: PATENT GRANTS TO PARTY 2
- Party 2's publication qualifies as prior art under 35 U.S.C. 102(a)(1) and does not fall within exclusion under 35 USC 102(b) with respect to Party 1
- Party 1's application qualifies as prior art under 35 U.S.C. 102(a)(1), but falls within exclusion under 35 USC 102(b)(1)(B) with respect to Party 2

Scenario 13: Unusual situation



- **Old 102**: PATENT GRANTS TO PARTY 1
- **New 102**: PATENT GRANTS TO PARTY 2
- Party 2's publication qualifies as prior art under 35 USC 102(a)(1), but may fall within exclusion under 35 USC 102(b)(1)(A)
- Party 1's application qualifies as prior art under 35 USC 102(a)(2), but may fall within exclusion under 35 USC 102(b)(1)(B)
- Can both patents issue? Can party 1 initiate derivation proceedings? What other recourse does Party 1 have?

QUESTIONS?

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BEARMAN, CALDWELL & BERKOWITZ, PC

Inequitable Conduct after *Therasense &* In Light of the New Supplemental Examination Provisions of the America Invents Act

D. Christopher Holly, Ph.D., J.D.
Intellectual Property Group
Washington, D.C.

EXPAND YOUR EXPECTATIONS™

Inequitable Conduct after *Therasense*

- Inequitable Conduct: A Brief History
  - Supreme Court Precedent
  - Trilogy of Federal Circuit Cases
- *Therasense* Decision
  - Materiality Standard
    - But-for
    - Affirmative Egregious Misconduct
  - Intent Standard
- Post-*Therasense*
- AIA Supplemental Examination
- Practical Advice for Prosecution

Inequitable Conduct: A Brief History

Supreme Court Precedent

- Inequitable conduct arose from unclean hands
- Early Inequitable Conduct Cases Involved Egregious Misconduct
  - **Suppression of evidence**: Patentee paid a prior user to sign a false affidavit (*Keystone Driller Co.*, 290 U.S. 240 (1933))
  - **Manufacture of false evidence**: Patentee's attorneys covertly authored article touting the invention (*Hazel-Atlas Glass Co.* 322 U.S. 238 (1944))
  - **Perjury**: Inventor gave false dates to the PTO regarding conception and reduction to practice (*Precision Instruments Manufacturing*, 324 U.S. 806 (1945))
- Consequence: dismissal of the patent enforcement suit

Inequitable Conduct: A Brief History

Metamorphosis of a Doctrine

The Early Egregious Affirmative Acts of Misconduct

Materiality + Intent and the Sliding Scale

- Sliding Scale
  - *Am. Hoist & Derrick Co.*, 725 F.2d 1350 (Fed. Cir. 1984)
  - Strong showing materiality → requires less evidence of intent

Inequitable Conduct: A Brief History

Trilogy of Federal Circuit Cases

- Omission may constitute inequitable conduct
  - **DAYCO** (2003) – Non-disclosure of 2 items Material:
    1) Related pending family of cases which could have led to double patenting rejections;
    2) Examiner's rejection of a substantially similar Claim
  - No Inequitable Conduct Found: No intent for (1), Need trial on (2)
  - MPEP § 2001.06(b) amended in response to DAYCO

Inequitable Conduct: A Brief History

Trilogy of Federal Circuit Cases

- Omission may constitute inequitable conduct
  - **McKesson** (2007) – Non-disclosure of 3 items Material:
    1) Relevant prior art patent;
    2) Other Examiner's rejections in pending case citing to non-disclosed patent;
    3) Notice of Allowance issued by SAME Examiner in a CIP of the patent under examination
  - Inequitable Conduct Found

Inequitable Conduct: A Brief History

Trilogy of Federal Circuit Cases

- Omission may constitute inequitable conduct
  - **Larson** (2009) – Non-disclosure of 2 items Material:
    1) Only two of four Office Actions from pending applications cited to reexamination panel;
    2) Reference cited in non-disclosed Office Action
  - Court relied on DAYCO in finding Materiality because Office Actions pertained to Substantially Similar Claims
  - No Inequitable Conduct Found: Remand to determine deceptive intent

Inequitable Conduct: A Brief History

- From its beginnings as a doctrine rooted in common law "Unclean Hands" jurisprudence, Inequitable Conduct had now completed its 70 year transformation into the "Atomic Bomb" of patent law
  - Entire patent unenforceable
  - Infectious inequitable conduct
  - Incurable
  - Antitrust/unfair competition
  - "Overplayed": pled in nearly every case
  - "Absolute plague"
- Worse patents?
  - Patent applicants disclose too much prior art
  - Patent applicants fear mischaracterizing the art

Inequitable Conduct after *Therasense*

- Inequitable Conduct: A Brief History
  - Supreme Court Precedent
  - Trilogy of Federal Circuit Cases
- *Therasense* Decision
  - Materiality Standard
    - But-for
    - Affirmative Egregious Misconduct
  - Intent Standard
- Post-*Therasense*
- AIA Supplemental Examination
- Practical Advice for Prosecution

Therasense Decision

- En banc decision
  - ➢ Unanimous decision to strengthen intent prong
  - ➢ Unanimous decision to eliminate “sliding scale”
- Majority decision to strength materiality standard

Therasense Decision

- Brief Facts: Involved test strips to monitor blood glucose and discrepancies in argument regarding how to distinguish a prior patent
- Abbott was trying to distinguish its currently pending test strip application, which issued as the '551 patent-in-suit, from a previously granted patent covering similar technology, '382 patent
- Re: '382 Patent's teachings "optionally, but preferably…a protective membrane (is present)"
  - Abbott's EP Counterpart Application: Attorney argued that '382 patent **did not require** protective membrane, and thus taught strips with no membrane covering.
  - US Case: Attorney argued '382 patent did not teach unprotected strips and a PHOSITA would understand that a membrane **was required**
  - EP Arguments not submitted to USPTO in US case

Majority Opinion

- Discussed the roots of inequitable conduct in the unclean hands doctrine
- Standards for intent and materiality have been reduced over the years to encourage disclosure to the PTO
  - "Numerous unforeseen and unintended consequences" in both litigation and prosecution
  - "Plagued not only the courts but also the entire patent system"
- "This court now **tightens the standards for finding both intent and materiality** in order to redirect a doctrine that has been overused to the detriment of the public."

Therasense Majority on Inequitable Conduct Litigation . . .

- The Federal Circuit was hostile to inequitable conduct doctrine, characterizing it as:
  - "atomic bomb"
  - "overplayed"
  - "cluttering up the patent system"
  - "overused to the detriment of the public"
  - "metastasized"

Perceived Evils of the Inequitable Conduct Standard

- "Low standards for intent and materiality have inadvertently led to many unintended consequences:
  - increased adjudication cost and complexity,
  - reduced likelihood of settlement,
  - burdened courts,
  - strained PTO resources,
  - increased PTO backlog, and
  - impaired patent quality."

Majority – Materiality

- Rejected PTO Rule 56 standard
  - "overly broad" and set "a low bar for materiality"
- Adopted "but-for" standard
  - Exception for "affirmative egregious misconduct"

Materiality Standard

- "But-for" Standard
  - Sounds Easy
- Play-within-Play
  - Establish by clear and convincing evidence that:
    - "But-for" the omission a reasonable examiner would not have allowed the claims when applying
      - A preponderance of the evidence standard giving the Claims the broadest reasonable interpretation
- Affirmative Egregious Misconduct – "But-for" Not Required

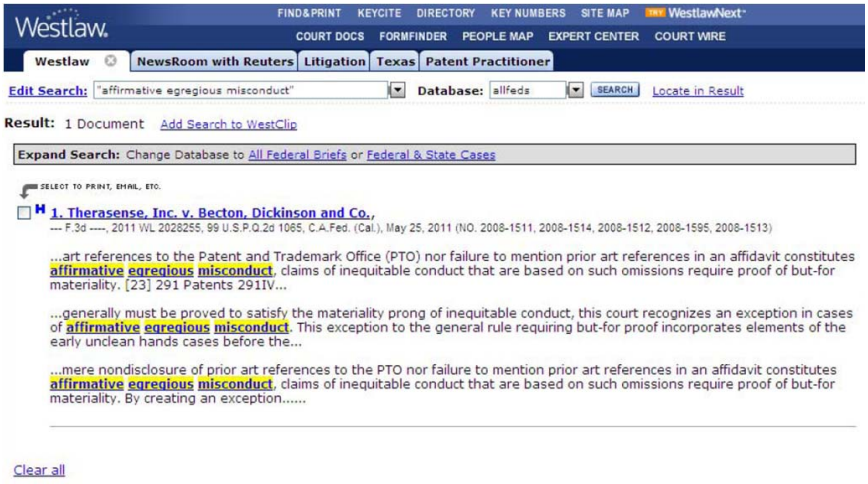
Majority – Intent

- Must show specific intent to deceive PTO
  - Negligence not enough
- No sliding scale
  - I.e. High materiality cannot substitute for intent
- Circumstantial evidence OK, but deceptive intent must be:
  - "single most reasonable inference"
  - If multiple reasonable inferences - intent cannot be found
- Patentee need not offer good faith explanation

"Specific intent to deceive the PTO"

- Requires clear and convincing evidence that:
  - Applicant "knew of the [withheld materials]";
  - Applicant "knew of their materiality"; AND
  - Applicant "made the conscious decision not to disclose them in order to deceive the PTO."
- Negligence is not enough
  - Not enough that Applicant knew of the reference, should have know of its materiality, and decided not to disclose
  - A return to the last *en banc* IC decision - *Kingsdown* (1988)? Will it last?

Exception for "affirmative egregious misconduct"



Inequitable Conduct after *Therasense*

- Inequitable Conduct: A Brief History
  - Supreme Court Precedent
  - Trilogy of Federal Circuit Cases
- *Therasense* Decision
  - Materiality Standard
    - But-for
    - Affirmative Egregious Misconduct
  - Intent Standard
- Post-*Therasense*
- AIA Supplemental Examination
- Practical Advice for Prosecution

Post-*Therasense*: What Can We Expect?

- Litigation Perspective
  - Fewer inequitable conduct trials
  - *Exergen* + *Therasense* = less IC allegations?
  - Increased summary adjudication against IC claims
  - Greater focus on early discovery re possible IC
  - Possible sanctions against attorneys who persist in maintaining frivolous IC allegations (*See Pfizer Inc. v. Teva Pharmaceuticals USA, Inc., (E.D. Va. Oct. 17, 2011*)

Post-*Therasense*: What Can We Expect?

- Prosecution Perspective
  - "Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found"
  - Generally business as usual, perhaps Prosecutors may sleep better at night
  - Possibly Solves McKesson Dilemma: A Request for Continued Examination (RCE) can affect Patent Term Adjustment and is therefore a reason to not disclose information, which has nothing to do with deceiving the PTO, also Office Actions are now filtered thru a "but-for" standard

Post-*Therasense*: What Can We Expect?

- PTO proposed revisions to Rule 56:
  - "Information is material … if material under … *Therasense*"
  - "…material…under *Therasense* if…Office would not allow a claim if it were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction … or… the applicant engages in egregious misconduct before the Office…"

Inequitable Conduct after *Therasense*

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35 USC § 257 Supplemental Examination

(a) REQUEST FOR SUPPLEMENTAL EXAMINATION

- A patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent
- Within 3 months after the date a request for supplemental examination is received, the Director shall conduct the supplemental examination and shall conclude such examination by:
  - issuing a certificate indicating whether the information presented in the request raises a substantial new question of patentability.

35 USC § 257 Supplemental Examination

(b) REEXAMINATION ORDERED

- If the certificate issued under subsection (a) indicates that a ***substantial new question*** of patentability is raised by 1 or more items of information in the request, the Director shall order reexamination of the patent. . . .

35 USC § 257 Supplemental Examination

(c) EFFECT

- (1) A patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent.

35 USC § 257 Supplemental Examination

(c) EFFECT

- (2) EXCEPTIONS
  - (A) PRIOR ALLEGATIONS
    - Shall not apply to an allegation pled with particularity in a civil action…or an allegation contained in a Paragraph 4 notice under the Hatch-Waxman Act…before the date of a supplemental examination request

35 USC § 257 Supplemental Examination

(c) EFFECT

- (2) EXCEPTIONS
  - (B) PATENT ENFORCEMENT ACTIONS
    - In an action brought under section 337(a) of the Tariff Act (ITC Case) **or** section 281 of this title (Infringement Civil Action):
      - Paragraph (1) shall not apply (Ineq. Cond. Inoculation) to any defense raised in the action that is based upon information that was considered, reconsidered, or corrected pursuant to a supplemental examination request under subsection (a), ***unless*** the supplemental examination, and any reexamination ordered pursuant to the request, are concluded before the date on which the action is brought.

35 USC § 257 Supplemental Examination

(e) FRAUD

- If the Director becomes aware, during the course of a supp. exam., that a **material fraud** on the Office may have been committed in connection with the patent, then:
  - the Director *may* cancel any claims found to be invalid
  - the Director ***shall*** also refer the matter to the Attorney General
    - "The Office regards the term "material fraud" to be narrower in scope than inequitable conduct as defined by the Fed. Cir. in *Therasense"*
    - Perhaps "affirmative egregious misconduct"??

Supplemental Examination Proposed Requirements

- Identification of the patent at issue
- A list of each item of information on which Supp. Ex. is requested
- A list identifying any other prior or concurrent post Patent Office proceedings involving the patent to be examined
- An identification of each aspect of the patent to be examined (Specification, Claims, Drawings, Priority, etc...)
- An identification of each issue raised by each item of information
- A separate, detailed explanation for each identified issue
- An explanation of how each item of information is relevant to each aspect of the patent to be examined and of how each item of information raises each identified issue (Claims Charts suggested)

Supplemental Examination Proposed Requirements

- The request must be filed by the patent owner
- Only the patent owner will be permitted to participate in the supplemental examination or any reexamination ordered
- Each request may identify up to ten items of information
- Multiple supplemental examination requests may be filed
- The cost for filing a supplemental examination request is steep:
  - **$5,180** for the initial request *plus* **$16,120** for the *ex parte* re-examination fee (**Total: $21,300**)
    - Both must be paid at the time of initial request, and the $16,120 will be refunded if no re-examination is ordered in the supplemental examination certificate

Inequitable Conduct after *Therasense*

- Inequitable Conduct: A Brief History
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  - Trilogy of Federal Circuit Cases
- *Therasense* Decision
  - Materiality Standard
    - But-for
    - Affirmative Egregious Misconduct
  - Intent Standard
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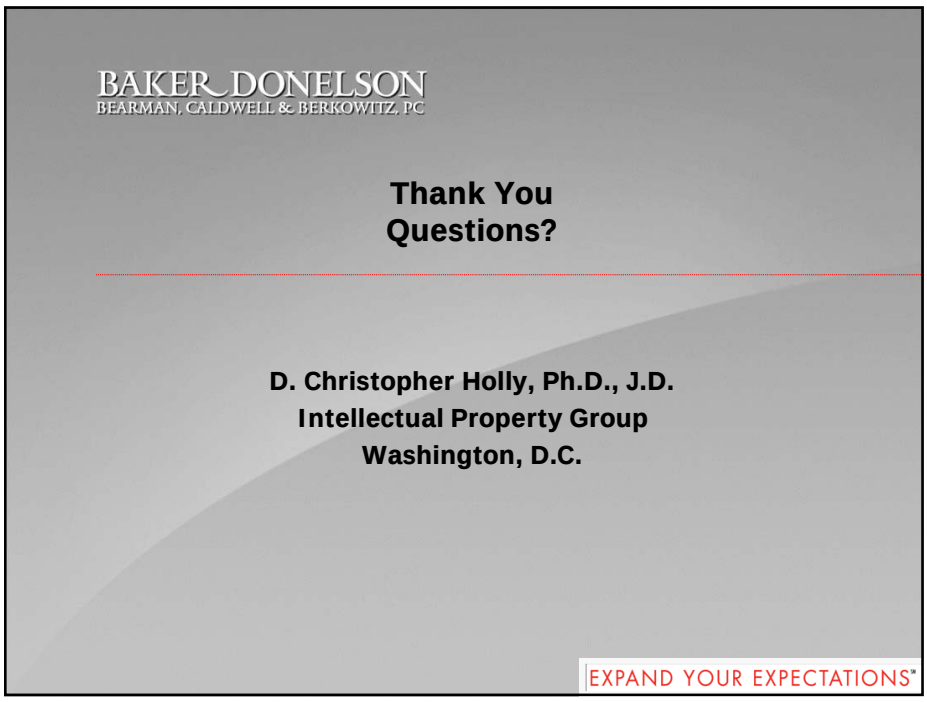
- Practical Advice for Prosecution

Practical Advice for Prosecution

- Hopefully *Therasense* eases the specter of Inequitable Conduct charges
- Should be easier to justify not reference dumping on the PTO in light of "but-for" materiality standard
  - However, PTO has yet to act on proposed Rule 56
- Supplemental Examination was much more valuable before *Therasense*
  - However, still beneficial in the appropriate cases
  - Must make sure Request is perfect, or else risk not receiving a filing date, in which case a competitor may file civil action based on such conduct and pre-empt the possibility of IC inoculation


BAKER DONELSON
BEARMAN, CALDWELL & BERKOWITZ, PC
Thank You
Questions?
D. Christopher Holly, Ph.D., J.D.
Intellectual Property Group
Washington, D.C.
EXPAND YOUR EXPECTATIONS™

BAKER DONELSON
BEARMAN, CALDWELL & BERKOWITZ, PC

Anatomy 2011: Dissecting 12 Months of the Court of Appeals for the Federal Circuit Jurisprudence

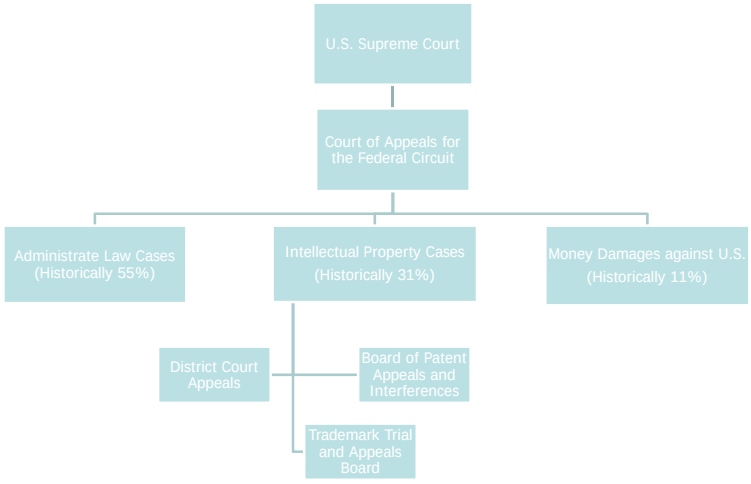
Sam Miller - Shareholder
Intellectual Property and Technology Litigation

EXPAND YOUR EXPECTATIONS™

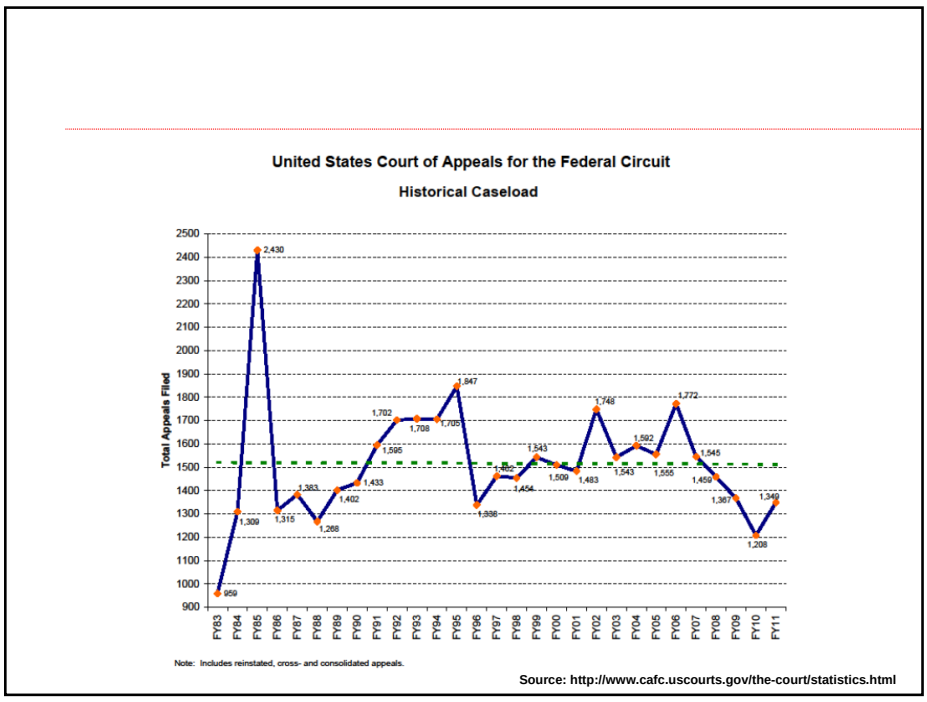
Sam Miller

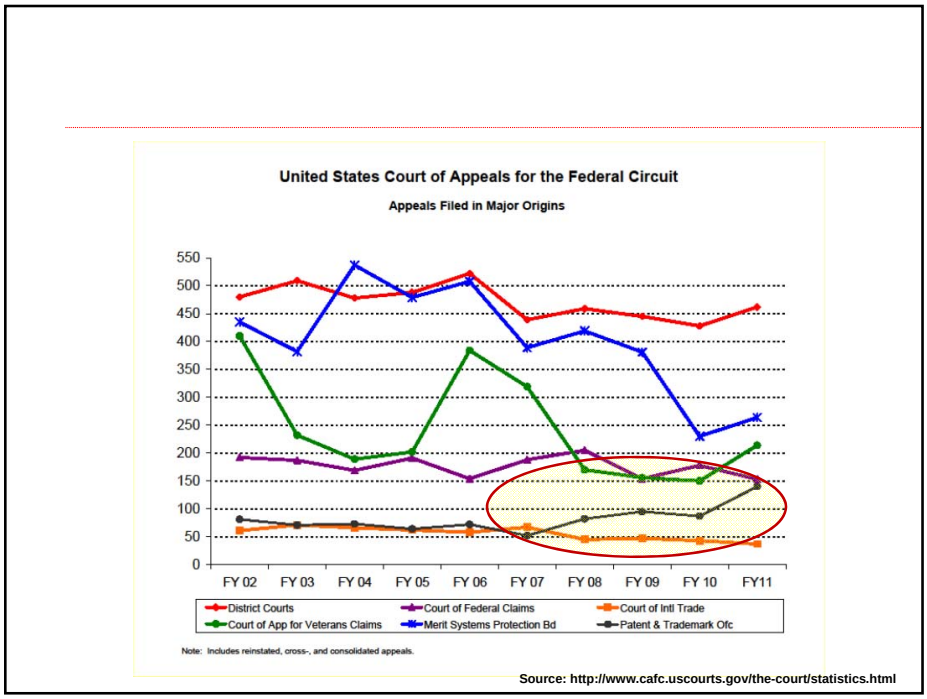
- Shareholder—Intellectual Property and Technology Litigation
- Lead counsel for a wide range of clients from individuals to small businesses to Fortune 500 companies in patent, copyright, trademark, trade dress, false advertising, and technology-related litigation
- Extensive experience in state and federal courts throughout the United States, including recent cases in the Southern District of New York; the Northern District of Georgia; Central and Northern Districts of California; the Eastern District of Texas; and the Middle, Western and Eastern Districts of Tennessee

What is the Court of Appeals for the Federal Circuit?



Federal Circuit Trends


United States Court of Appeals for the Federal Circuit
Historical Caseload
Total Appeals Filed
2500
2400
2300
2200
2100
2000
1900
1800
1700
1600
1500
1400
1300
1200
1100
1000
900
2,430
1,847
1,772
1,748
1,708
1,705
1,702
1,595
1,592
1,545
1,543
1,555
1,509
1,483
1,459
1,457
1,454
1,433
1,402
1,383
1,367
1,349
1,343
1,315
1,309
1,268
1,208
959
FY83
FY84
FY85
FY86
FY87
FY88
FY89
FY90
FY91
FY92
FY93
FY94
FY95
FY96
FY97
FY98
FY99
FY00
FY01
FY02
FY03
FY04
FY05
FY06
FY07
FY08
FY09
FY10
FY11
Note: Includes reinstated, cross- and consolidated appeals.
Source: http://www.cafc.uscourts.gov/the-court/statistics.html


United States Court of Appeals for the Federal Circuit
Appeals Filed in Major Origins
550
500
450
400
350
300
250
200
150
100
50
0
FY 02
FY 03
FY 04
FY 05
FY 06
FY 07
FY 08
FY 09
FY 10
FY11
District Courts
Court of Federal Claims
Court of Intl Trade
Court of App for Veterans Claims
Merit Systems Protection Bd
Patent & Trademark Ofc
Note: Includes reinstated, cross-, and consolidated appeals.
Source: http://www.cafc.uscourts.gov/the-court/statistics.html

United States Court of Appeals for the Federal Circuit

Median Time to Disposition in Cases Terminated After Hearing or Submission[1]

Docketing Date[2] to Disposition Date, in Months

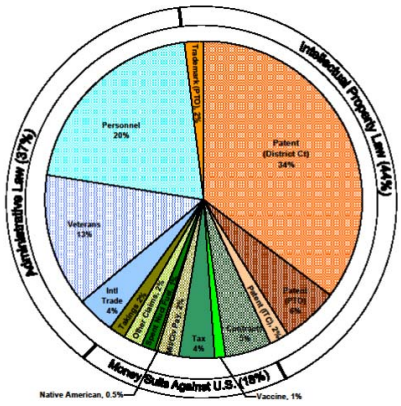
	FY 02	FY 03	FY 04	FY 05	FY 06	FY 07	FY 08	FY 09	FY 10	FY 11	Overall Median per Origin
District Court	12.3	11.3	11.7	11.6	11.5	11.6	11.0	11.0	11.0	11.2	11.4
Court of Federal Claims	11.4	9.8	11.0	11.2	10.0	10.0	9.2	10.3	10.0	10.6	10.4
Court of International Trade	14.7	11.2	12.0	11.5	11.7	11.9	12.4	11.5	11.0	12.2	11.8
Court of Appeals Veterans Claims	12.9	10.6	10.0	9.9	8.4	8.4	8.0	9.3	9.3	6.0	9.0
Board of Contract Appeals	11.3	12.6	9.7	10.5	11.7	10.4	9.6	11.9	8.8	10.0	11.0
Department of Veterans Affairs	11.1	13.8	n/a	14.4	13.7	11.3	4.8	18.9	n/a	19.4	13.6
Department of Justice	n/a	n/a	n/a	n/a	n/a	n/a	n/a	8.9	8.9	n/a	8.9
International Trade Commission	n/a	17.1	16.0	16.4	15.6	13.6	14.4	14.4	14.8	14.6	14.9
Merit Systems Protection Board	7.2	7.6	6.9	7.5	6.5	6.4	5.8	6.5	6.1	6.1	6.7
Office of Compliance	n/a	19.6	10.1	13.3	14.0	n/a	19.0	n/a	13.0	15.0	13.6
Patent and Trademark Office	10.7	9.5	9.6	10.3	10.0	9.6	8.9	9.3	8.2	11.2	9.6
Overall Median per Fiscal Year	10.5	9.6	10.0	9.9	9.3	9.1	9.0	9.3	9.3	9.7	

[1] Excludes cross and consolidated appeals, writs, and OPM petitions
[2] Calculated from Date of Docketing or Date of Reinstatement, whichever is later

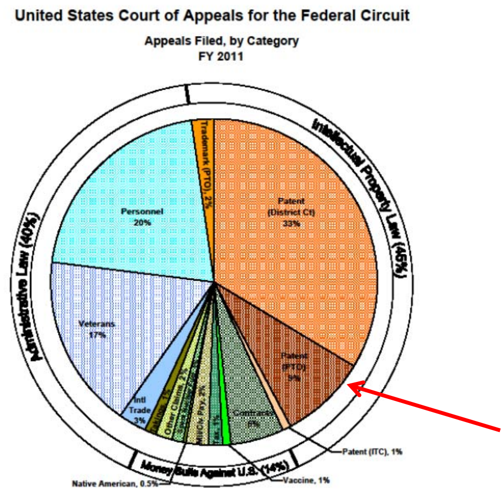
Source: http://www.cafc.uscourts.gov/the-court/statistics.html

United States Court of Appeals for the Federal Circuit

Appeals Filed, by Category
FY 2010



Source: http://www.cafc.uscourts.gov/the-court/statistics.html



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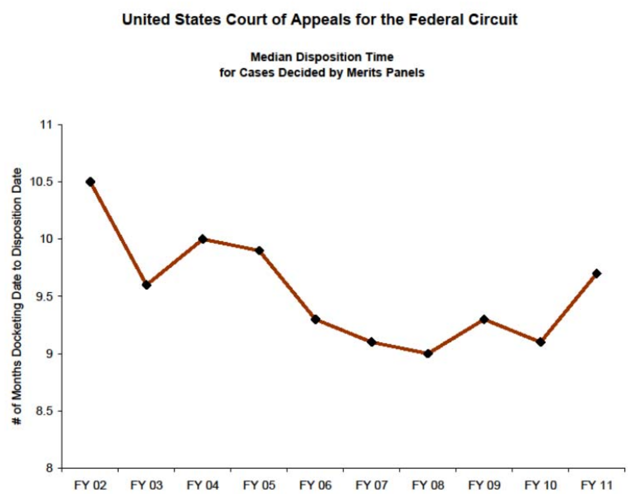


Source: http://www.cafc.uscourts.gov/the-court/statistics.html

Table B-8.
U.S. Court of Appeals for the Federal Circuit--Appeals Filed, Terminated, and Pending
During the Twelve-Month Period Ended September 30, 2011

Source of Appeals	Pending 1-Oct-10	Filed	Terminations Total	By Judges	Other	Percent Reversed	Pending 30-Sep-11
Total	910	1,349	1,347	901	346	13	1,012
Board of Contract Appeals	9	20	12	9	3	25	17
U.S. Court of International Trade	43	37	40	37	3	39	40
U.S. Court of Federal Claims	169	153	209	164	45	16	113
U.S. Court of Appeals for Veterans Claims	111	214	197	148	49	3	128
U.S. District Courts	365	462	421	291	130	14	406
Department of Justice	0	0	0	0	0	0	0
Department of Veterans Affairs	5	4	4	2	2	0	5
International Trade Commission	24	11	18	13	5	27	17
Merit Systems Protection Board	109	264	219	140	79	5	154
Office of Compliance	2	2	3	3	0	0	1
Patent & Trademark Office	58	140	78	52	26	14	120
Writs*	15	42	46	42	4	0	11

*THIS CATEGORY INCLUDES WRITS OF MANDAMUS, OTHER EXTRAORDINARY WRITS, PETITIONS FOR PERMISSION TO APPEAL, AND DISCRETIONARY PETITIONS FOR REVIEW.

Source: http://www.cafc.uscourts.gov/the-court/statistics.html

United States Court of Appeals for the Federal Circuit

Year-to-Date Activity and Status of Pending Appeals
as of January 27, 2012

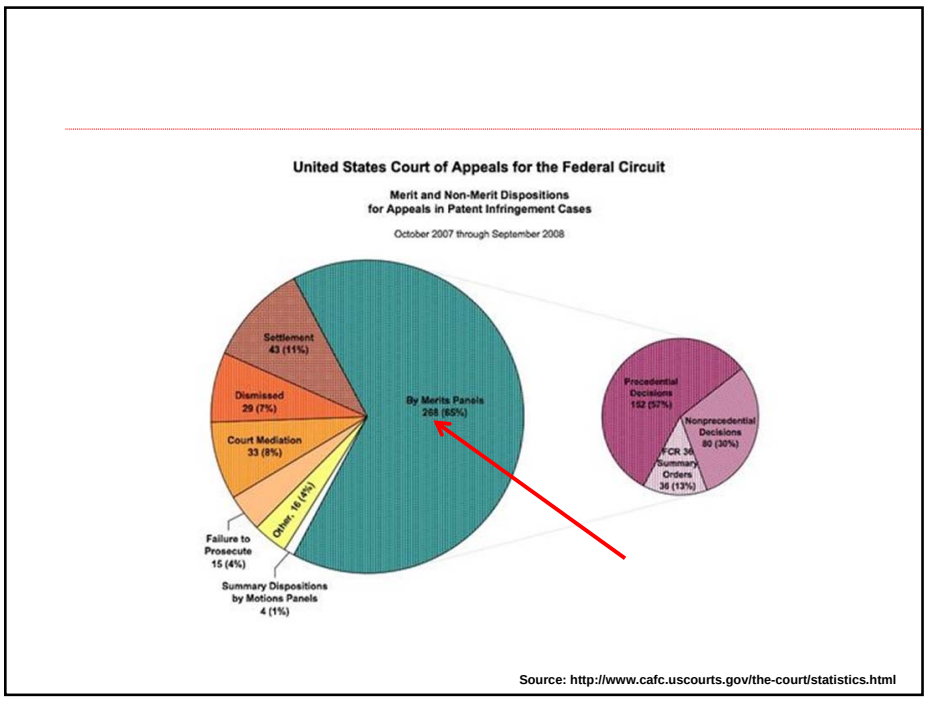
Year-to-Date Activity

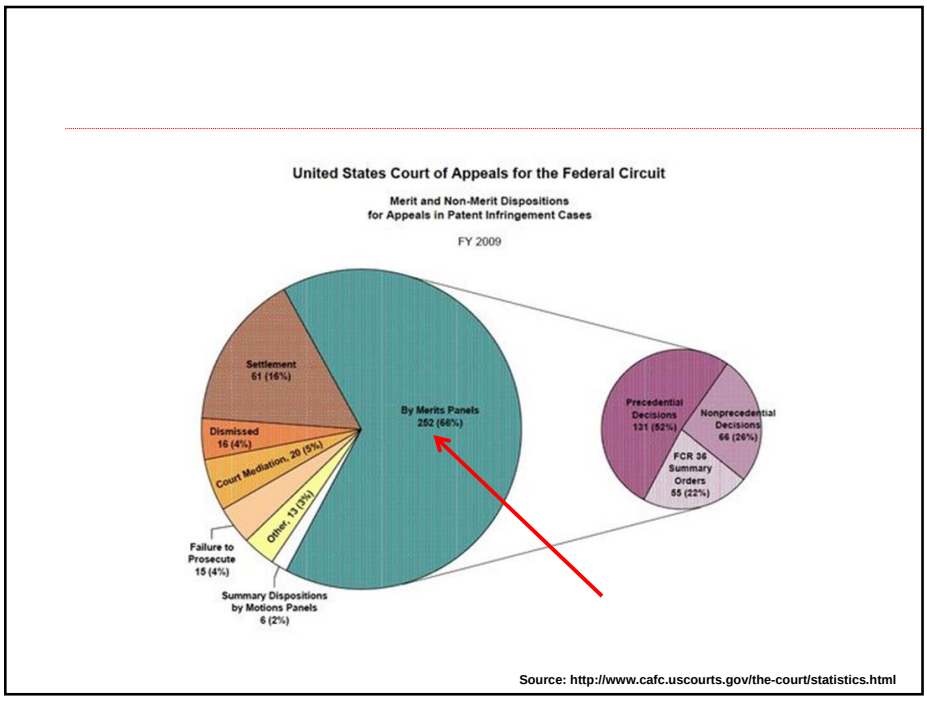
Court or Agency of Origin	Pending as of 10/01/11	Docketed 10/01/11 to date	Terminated 10/01/11 to date	Currently Pending
Boards of Contract Appeals	17	5	5	17
Court of Federal Claims	113	81	47	127
Court of International Trade	40	10	9	41
Court of Appeals for Veterans Claims	128	63	62	129
District Courts	405	136	123	419
Department of Justice	0	0	0	0
Department of Veterans Affairs	5	0	4	1
International Trade Commission	17	7	5	19
Merit Systems Protection Board	154	80	93	141
Office of Personnel Management	0	0	0	0
Office of Compliance	1	1	0	2
Patent & Trademark Office	120	29	42	107
Writs	11	13	16	8
TOTAL	1012	405	406	1011

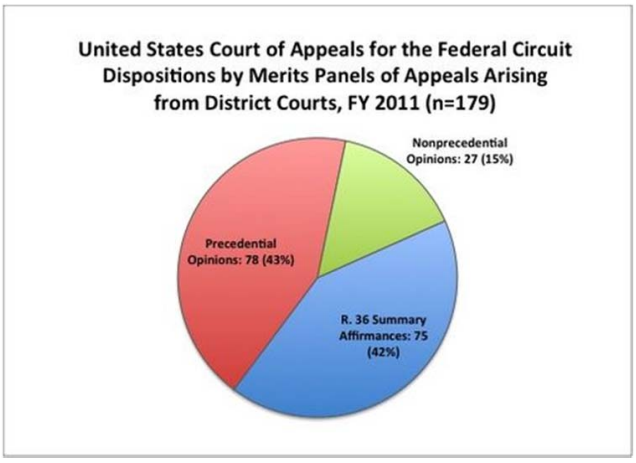
Status of Pending Appeals

Under submission to merits panels	112
On upcoming calendar(s)	158
Ready for calendaring	47
Awaiting later briefs	235
Awaiting first brief	391
Briefing stayed	68
	1011

Source: http://www.cafc.uscourts.gov/the-court/statistics.html

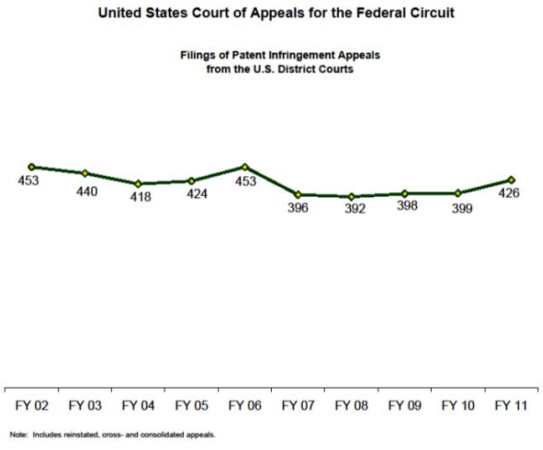

United States Court of Appeals for the Federal Circuit
Merit and Non-Merit Dispositions
for Appeals in Patent Infringement Cases
October 2007 through September 2008
Settlement
43 (11%)
Dismissed
29 (7%)
Court Mediation
33 (8%)
Other, 16 (4%)
Failure to
Prosecute
15 (4%)
Summary Dispositions
by Motions Panels
4 (1%)
By Merits Panels
268 (65%)
Precedential
Decisions
152 (57%)
Nonprecedential
Decisions
80 (30%)
FCR 36
Summary
Orders
36 (13%)
Source: http://www.cafc.uscourts.gov/the-court/statistics.html


United States Court of Appeals for the Federal Circuit
Merit and Non-Merit Dispositions
for Appeals in Patent Infringement Cases
FY 2009
Settlement
61 (16%)
Dismissed
16 (4%)
Court Mediation, 20 (5%)
Other, 13 (3%)
Failure to
Prosecute
15 (4%)
Summary Dispositions
by Motions Panels
6 (2%)
By Merits Panels
252 (68%)
Precedential
Decisions
131 (52%)
Nonprecedential
Decisions
66 (26%)
FCR 36
Summary
Orders
55 (22%)
Source: http://www.cafc.uscourts.gov/the-court/statistics.html



Source: Jason Ratanen, Patently-O blog, www.patentlyo.com (October 27, 2011):

Increase in Patent Infringement Appeals in 2011



Noteworthy Federal Circuit Decisions in 2011

Wellman, Inc. v. Eastman Chem Co. (April 29, 2011)

- **Issue**: Whether an applicant may hold back the actual best mode as a trade secret.
- **Result**: The Federal Circuit held that an applicant must disclose the best mode and may not hide it as trade secret.

Therasence Inc. v. Becton, Dickinson & Co. (May 25, 2011)

- **Issue**: What is the standard for establishing the inequitable conduct defense?
- **Result**: The Federal Circuit held (1) an omitted reference is a material reference only if "but for" its exclusion the claim or patent would not have issued; (2) there must be clear and convincing evidence of a specific intent to deceive by the applicant; and (3) a court cannot use a "sliding scale" to find inequitable conduct.

Kimberly-Clark v. First Quality Baby Products (June 1, 2011 – en banc denied)

- **Issue**: What is the appropriate standard for the likelihood of success prong in a request for preliminary injunctive relief?
- **Result**: The Federal Circuit vacated district court's injunction order and applied the standard that an applicant for relief fails to establish a likelihood of success on the merits if the accused party raises a defense that "does not lack substantial merit" and that such failure precludes entry of a preliminary injunction.

Molecular Pathology v. Myriad Genetics, Inc. (July 29, 2011)

- **Issue #1**: Whether a party who disagrees with the existence of a certain patent or who suffers an attenuated, non proximate effect from the existence of the patent, has standing to challenge the validity of the patent through a declaratory judgment action.
- **Result**: The Federal Circuit held that the "inability to afford a patented invention" does create an invasion of a legally protected interest that is sufficient to create standing.

Molecular Pathology v. Myriad Genetics, Inc. (continued)

- **Issue #2**: Whether claims to "isolated" DNA and methods of using that "isolated" DNA are eligible to be patented under 35 U.S.C. § 101.
- **Result**: The Federal Circuit held that (1) isolated DNA molecules are patent eligible; and (2) certain method claims related to "isolated" DNA are patent eligible.
  - method claims directed to only "comparing" or "analyzing" DNA sequences **= ineligible**
  - a method that comprises the steps of (1) "growing" host cells transformed with an altered gene in the presence or absence of a potential therapeutic, (2) "determining" the growth rate of the host cells with or without the potential therapeutic and (3) "comparing" the growth rate of the host cells includes more than the abstract mental step of looking at two numbers and "comparing" two host cells' growth rates **= eligible**

The most important cases in Federal Circuit jurisprudence in 2011 actually may be the appeals granted from 2010 decisions.

Caraco Pharm. Labs., Ltd. v. Novo Nordisk (A/S) (April 14, 2010)

- **Issue**: Whether the counterclaim provision of the Hatch-Waxman Act (21 U.S.C. § 355(j)(5)(C)(ii)(I)) authorizes a generic drug manufacturer in a patent infringement suit to assert a counterclaim compelling the patent holder to modify an overly broad description of its patent?
- **Result**: The Federal Circuit found (1) the counterclaim provision of the Act was limited to situations where the listed patent did not claim any of the approved methods of using the drug, and (2) the provisions permitting counterclaims were limited to improper listing of "patent information" as covering approved methods of using a drug and that use codes were not "patent information" as defined by the statute.
- **Cert. Granted by Supreme Court**

Kappos v. Hyatt (November 8, 2010)

- **Issue**: Whether a plaintiff, who is appealing the denial of an application for a patent by commencing a civil action against the Director of the USPTO in a federal district court pursuant to 35 U.S.C. § 145 may introduce new evidence that could have presented to the USPTO during the prosecution.
- **Result**: Yes, new evidence may be introduced.
- **Cert. Granted by Supreme Court**

Akamai Tech., Inc. v. Limelight Networks, Inc. (December 2, 2010)

- **Issue**: If separate entities each perform separate steps of a method claim, under what circumstances would that claim be directly infringed and to what extent would each of the parties be liable?
- **Result**: To be determined because en banc decision to follow.

Mayo Collaborative Services. v. Prometheus (December 17, 2010)

- **Issue**: Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve transformations of body chemistry.
- **Result**: The Federal Circuit found Prometheus' claims to recite patentable subject matter under 35 U.S.C. § 101.
- **Cert. Granted by Supreme Court**

Questions?

BAKER DONELSON
BEARMAN, CALDWELL & BERKOWITZ, PC

HOT TOPICS IN TRADEMARK LAW

Micheline Kelly Johnson
March 22, 2012

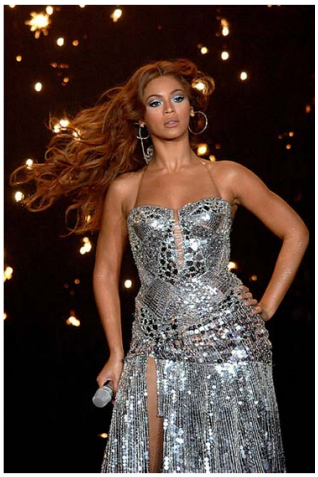
EXPAND YOUR EXPECTATIONS™

Faith Ladd, five year old

Celebrity Trademark Watch:

- *Is it possible to hip hop to the front of the line?*

Beyonce'



Blue Ivy Carter NYC

Jeremy Lin

LINSANITY

- Yenchin (Matthew) Chang
- Andrew Slayton
- Yoonsoo Stephen Kim
- Wesley Kwong-Yew Tang
- Roger Montgomery
- Jeremy Lin

Court tells Louboutin to take a hike

How to protect your brand without being a trademark bully:

lessons from the North Face and Coke


THE NORTH FACE
THE SOUTH BUTT


facebook
Home
Profile
Friends
Inbox 12
Coca-Cola
Become a Fan
Wall
Info
Photos
Video
Discussions
Coca-Cola Fans
Just Coca-Cola
Just Fans
Mice Isolanib ▶ MEET NEW FRIENDS AT E-MAIL CLUB
http://www.graphicstylist.com/email_club.htm
3 minutes ago · Report
Nitzan Taary
13 minutes ago · Report
Danny Buehs coca cola la mejor del mundo
14 minutes ago · Report
Caroline Maissin Enigme: qui boit plus de 2Litres de
sans s'en rendre compte ??!!
Become a Fan

Charbucks wins Round 3 with Starbucks

STARBUCKS COFFEE ®

V.

Round 3

How can a trademark owner protect itself against solicitations by unscrupulous companies?

Subject	Curr.	Amount
Charge o. registration	USD	2415,00
Extra charge	USD	0,00
Value added tax	USD	0,00
Total due ???	**USD**	**2415,00**

Please pay the amount above, on acceptance, within 10 days by wire transfer or cheque.

Price of the iPad name: $55,000 to $2Billion

BAKER DONELSON
BEARMAN, CALDWELL & BERKOWITZ, PC

Federal Public Policy Overview

Presented by

JC Sandberg and Laine Glisson Oliver

March 22, 2012

Baker, Donelson, Bearman, Caldwell and Berkowtiz, PC
920 Massachusetts Avenue, NW 9th FL
Washington, D.C. 200001
202.508.3400

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Who We Are—Baker Donelson Federal Policy Team

Senator Howard Baker Jr.
Strategy and Counsel

Congresswoman Nancy Johnson
Strategy and House Leadership

Janet Powell
Appropriations
Transportation

J. Keith Kennedy
Appropriations

Laine Glisson Oliver
Senate and House Leadership
All Congressional Committees

John Tuck
Energy

JC Sandberg
Environment & Transportation
Senate Leadership

John Kinney
Director of Research and Special Projects

Lance Leggitt

The Role of a Public Policy Practice

What We Do

- Help our clients understand the legislative and regulatory environment
- Work with clients to educate Washington policymakers and to build consensus with relevant officials and stakeholder groups on client initiatives through a coordinated multi-faceted advocacy strategy
- Maintain relationships and build credibility with key decision-makers in the Legislative and Executive Branch

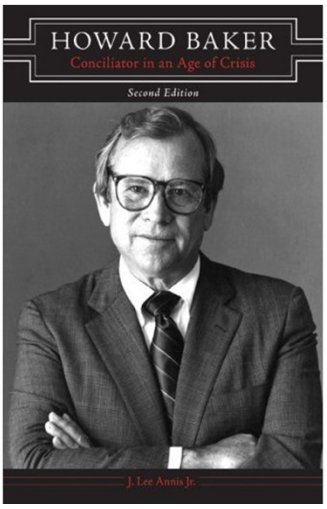
How We Do It

- Take full inventory of client's business model
- Conduct SWOT analysis—Strengths, Weaknesses, Opportunities, Threats
- Gather information—research, polling, forums
- Craft a compelling narrative and legislative strategy
- Form coalitions
- Communicate the message to federal policymakers
- Engage and Leverage media

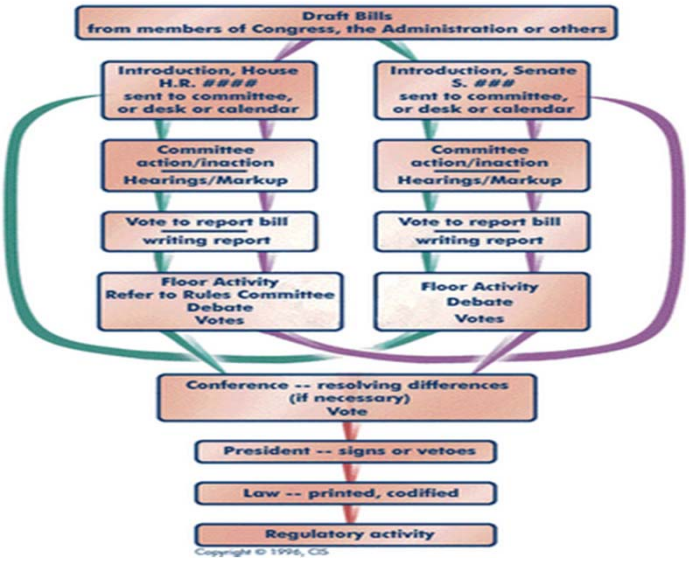
Conciliator in an Age of Crisis

"Known in Washington, D.C. as the 'Great Conciliator,' Baker is often regarded as one of the most successful senators in terms of brokering compromises, enacting legislation, and maintaining civility.

J. Lee Annis, Jr., on Howard Baker
September 28, 2007



An Example of What We Do: Patent Reform Bill



Why Engage in The Debate?

- Last fall's passage of the U.S. Patent Reform Act of 2011 represented the most significant patent care reform legislation in over forty years
- Regulatory changes and practice will begin to take shape in the coming year and will continue to evolve over the next several years
- As they emerge, these policy and implementation details will have a critical impact on the regulated industry
- There were winners and losers in the U.S. Patent Reform Act debate
- Continuing to maintain relationships with relevant decision-makers is critical to long-term legislative and regulatory success

Current Political Landscape

- House: - Republican Majority
  - Democrats 192
  - 242 Republicans
  - 1 Vacant
- Senate : Democratic Majority
  - 51 Democrats
  - 47 Republicans
  - 2 Independents
- Administration: Democratic
- Presidential Elections
- Mid-Term Elections

Legislative Outlook

Case Studies

- The Howard Baker Forum
- Health Savings Account
- Fast Track Drug Approval

The American Political Process

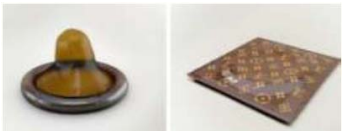
Q: "Dad, What Makes America Great?"

A: "That's Easy, Son. Its System of Endless Appeals"

Thank You for Smoking (Fox, 2005)

Be careful -- use trademark protection!

- The 60 euro Louis Vuitton condom:



Thank you!

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BEARMAN, CALDWELL & BERKOWITZ, PC

U.S. Post-Grant Practice & European Opposition Practice

A Brief Comparison

C.G. Moore, Ph.D.

Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C.
cmoore@bakerdonelson.com

EXPAND YOUR EXPECTATIONS™

Part One

- U.S. post-grant practice & changes under the AIA
  - What remains the same and what's new?
- *Practice and procedure*
- *European Opposition practice*

U.S. Post-Grant Review, Then & Now

Before:
- *Ex parte* reexam
- *Inter partes* reexam

Transition:
- *Ex parte* reexam (virtually unchanged)
- *Inter partes* reexam (phasing out)
- Post grant review (new)
- *Inter partes* review (new)

After:
- *Ex parte* reexam
- Post grant review
- *Inter partes* review
- Supplemental Examination

Changes to Post-Grant Review

- **Immediate Changes**
  - Standard for *inter partes* reexamination
    - SNQ no more
    - Now: "reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged."
- **September 16, 2012**
  - Post-Grant Review **begins** (for "covered business method patents")
  - *Inter partes* Review – all patents – **begins**
  - *Inter partes* Reexamination **ends**
  - Supplemental Examination **begins**

Changes to Post-Grant Review

- **March 16, 2013**
  - Post-Grant Review
    - For patents with an effective filing date on or after March 16, 2013
      - Must file PGR request within 9 months of issuance or re-issuance for broadening reissues (§ 321(c))
    - Applications with earlier effective filing dates are not eligible for Post-Grant Review
      - Exception for business method patents

Part Two

- *U.S. post-grant practice & changes under the AIA*
  - *What stays the same and what is new?*
- **Practice and procedure**
- *European Opposition practice*

Ex Parte Reexam (unchanged)

- **Eligibility**
  - Any patent in force
- **Requester**
  - Third parties, patent owner, USPTO Director
- **Scope**
  - § 102 & 103, based on printed publications & patents
- **Timing**
  - After issuance of patent
- **Threshold**
  - The Office determines that a "substantial new question of patentability" (SNQ) exists

Ex Parte Reexam (unchanged)

- **Other**
  - Requester can remain anonymous
  - No third-party participation
  - No discovery
  - No estoppel effect

Post-Grant Review (new proceeding)

- **Eligibility**
  - Patents having an effective filing date on or after March 16, 2013 (caveat: "covered business method patents")
- **Requester**
  - Third parties
- **Scope**
  - §§ 101, 102, 103, and 112 (but not best mode)
- **Timing**
  - Within 9 months from issuance of patent
- **Threshold**
  - "that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable"; **or**
  - there is a "showing that the petition raises a novel or unsettled legal question that is important to other patents or patent applications"

Post-Grant Review (new proceeding)

- **Other**
  - Requester must identify itself
  - Requester can submit affidavits & declarations, and has the right to an oral hearing
  - Discovery available; limited to "evidence directly related to factual assertions advanced by either party in the proceeding"
  - Requester estopped by prior PGR decision with respect to any ground that was or could have been raised

Inter Partes Review (new proceeding)

- **Eligibility**
  - Effective September 16, 2012; **applies to ANY patent** (replaces *inter partes* reexamination)
- **Requester**
  - Third parties
- **Scope**
  - § 102 & 103, based on printed publications & patents
- **Timing**
  - Nine months after issuance of patent, or after termination of Post-Grant Review
- **Threshold**
  - There is "a reasonable likelihood that petitioner would prevail with respect to at least one of the claims"

Inter Partes Review (new proceeding)

- **Other**
  - No longer before an examining corps; now before the PTAB
  - Requester must identify itself
  - Requester can submit affidavits & declarations, and has the right to an oral hearing
  - Discovery available; limited to deposition of witnesses submitting affidavits/declarations and "what is otherwise necessary in the interest of justice"
  - Requester estopped by prior IPR decision with respect to any ground that was or could have been raised
- N.B.: Limited to 281 proceedings per year, until 2016

Features Common to All

- Initial Determination
  - Petition filed by challenger
  - Patent owner may file response
  - USPTO issues decision on petition within 3 months of Patent Owner response (or deadline for response)
    - Not appealable

Features Common to IPR & PGR

- Conduct During Review
  - Before panel of judges at the PTAB
    - Removes Examiners from process
  - Limited discovery
  - Patent owner may amend the patent to:
    (1) Cancel a challenged claim; or
    (2) Propose a reasonable number of substitute claims
    - Similar to EP Opposition practice, and cuts down on new claim binges common in current inter partes practice
  - Each side will have chance to file comments and request an oral hearing
  - Final determination to issue within 1 year
    - USPTO may extend deadline by 6 months for good cause

Features Common to IPR & PGR

- Estoppel
  - If a review results in a final decision by the PTAB, the petitioner may not challenge the claim before the USPTO or court based on any ground the petitioner raised or reasonably could have raised
  - Changes
    - "Reasonably" could have raised
    - Attaches with Board decision, as opposed to final appeal
  - Estoppel does not attach in EP oppositions – still a big difference
  - Common (and unresolved) concerns:
    - That new art will be uncovered during discovery and trial prep
    - That post grant challenges will tie client's hand with respect to art turned up during discovery, but after start of a review

Comparison of Features

	***Ex parte* reexamination**	***Inter partes* reexamination**	**Post-grant review**	***Inter partes* review**
Timing	Any time post-issuance	Any time post-issuance	Within 9 months from grant (but before challenger files suit)	After 9 months from grant (but before challenger files suit)
Eligibility	Any patent	Any patent issued from an original application filed on or after Nov. 29, 1999	Patent filed under FITF - OR - Dismissed interference - OR - Business method patent	Any patent
Threshold	SNQ	Reasonable likelihood that requester would prevail	More likely than not that claim is unpatentable - OR - novel or unsettled legal question	Reasonable likelihood that the requester would prevail
Basis	Patents or printed publications	Patents or printed publications	Any ground possible in litigation under 35 USC § 282(b)(2) or (3) (including §§ 101, 102, 103, 112)	Patents or printed publications

Comparison of Features

	Ex parte reexamination	*Inter partes* reexamination	Post-grant review	*Inter partes* review
Anonymity	Yes	No	No	No
Interviews	Yes	No	No	No
Discovery	None	None	Limited	Limited
Time Limit on USPTO	None ("special dispatch")	None ("special dispatch")	One year (extendable to 18 months)	One year (extendable to 18 months)
Early termination	No	Possible	Joint request (specific to petitioner); any agreement must be submitted	Joint request (specific to petitioner); any agreement must be submitted
Estoppel	None	Any ground raised or that could have been raised	Any ground raised or reasonably could have been raised, unless settled	Any ground raised or reasonably could have been raised, unless settled
Intervening rights	Yes	Yes	Yes	Yes

Comparison of Features

	Ex parte reexamination	*Inter partes* reexamination	Post-grant review	*Inter partes* review
% completed with				
- claims amended	**65 %**	**42 %**		
- all claims confirmed	**23 %**	**11 %**	???	???
- all claims cancelled	**12 %**	**47 %**		

Part Three

- *U.S. post-grant practice & changes under the AIA*
  - *What remains the same and what's new?*
- *Practice and procedure*
- European Opposition Practice

European Opposition Practice

- Recall: a European Patent is a bundle of patents
  - After the opportunity to oppose before the EPO expires, the cost of country-by-country challenge is high
- Two avenues for challenge before EPO
  - Third Party Observations
  - Opposition

Third Party Observations

- Can file any time from publication through grant, and during appeal/opposition procedure
- Casts aspersions on the file, “helps” Examiners
- Inexpensive
- Can be anonymous
  - Third party is not a party to proceedings
- Can be very simple, or fully detailed and reasoned
  - Can make repeated observations

Opposition

- Roughly analogous to U.S. Post Grant Review
  - Same period: 9-month window after issuance
  - Same grounds: essentially, any unpatentability ground
- Requires a fully-reasoned case
- Requester is full party to proceedings; can attend all hearings
- About 5% of EP patents are opposed
  - How many U.S. patents will face PGR?
  - Recall: Estoppel does not attach in EP oppositions
  - Recall: Opposition is last chance to proceed before EPO

For more information, please contact:

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Warner J. Delaune, of counsel in the Firm's Baton Rouge office, is a member of Baker Donelson's Intellectual Property Group.

Through representation of both large and small companies, he has written and prosecuted numerous patent applications across a wide variety of technologies, including medical devices, sporting goods, firearms, watercraft, computer networking, wastewater treatment, recycling processes, metal cleaning and coating, electromechanical control systems, oil and gas extraction, and manufacturing equipment. Mr. Delaune also counsels clients in transactional matters involving intellectual property, including license agreements, joint ventures, and mergers and acquisitions. In addition, he handles intellectual property litigation matters in both federal and state court. He is a registered patent attorney licensed to practice before the United States Patent and Trademark Office in patent cases.

Mr. Delaune received his undergraduate degree from Louisiana State University in mechanical engineering, and he was employed with Texas Instruments, Inc., in the Defense Systems and Electronics Group, where he designed infrared systems for use on military vehicles. He also participated in flight testing of those systems on both fixed wing aircraft and helicopters.

Representative Matters

- Counsel to software company sold to global CAD/CAM developer.
- Management of international patent portfolios for clients in recycling, rotary seals, shipbuilding, and construction equipment.
- Counsel to universities in wide range of research and development projects.
- Counsel to pharmaceutical startup in technology license and private placement.
- Counsel to technology companies in equity investment transactions involving license agreements, joint development agreements, and supply agreements.

Professional Honors & Activities

- AV® Preeminent™ Peer Review Rated by Martindale-Hubbell
- Listed in *The Best Lawyers in America*® in the areas of Intellectual Property Law since 2009 and Technology Law (2009 – 2010, 2012)
- Member – Advisory Board, Louisiana Business and Technology Center at Louisiana State University (2006 – 2008)
- Member – Louisiana Technology Council

- Member – Louisiana State Bar, Section on Intellectual Property
- Member –American Bar Association, Section on Intellectual Property
- Member – American Intellectual Property Law Association
- Recipient – Baker Donelson's 2011 Baton Rouge Office Pro Bono Award
- Past Assistant Instructor – Engineering Graphics, Louisiana State University

Admissions

- Louisiana, 1991
- U.S. District Courts, for the Middle, Eastern, and Western Districts of Louisiana
- U.S. Patent and Trademark Office

Education

- Paul M. Hebert Law Center at Louisiana State University, J.D., 1991
- Louisiana State University, B.S., 1986. Received Outstanding Senior Design Project award for a veterinary spinal testing device, 1985.

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Richard Henderson is a registered patent attorney in the Firm's Washington, D.C., office. Dr. Henderson has significant experience in patent prosecution; the preparation and negotiation of agreements including license, consulting and secrecy agreements; trademark review and prosecution; and other intellectual property issues such as patentability, validity and infringement opinions.

Prior to joining Baker Donelson, Dr. Henderson served as senior patent counsel and head of the patent group for nine years at Bayer CropScience LP and as patent counsel for 14 years at Bayer Corporation, where he was responsible for intellectual property matters for Bayer's Industrial Chemicals Division. Prior to Bayer, he worked as a patent attorney with Merck and as a patent agent with G. D. Searle.

Admissions

- New Jersey (1987)
- U.S. Patent and Trademark Office, No. 31619 (1984)

Education

- Chicago-Kent College of Law, J.D., 1987, with honors
- University of Illinois, Urbana-Champaign, Ph.D., 1973
- University of North Carolina, Chapel Hill, B.S., 1967

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David L. Vanik, Ph.D., associate in Baker Donelson's Washington, D.C., office, is a member of the Firm's Intellectual Property Group. As a registered patent attorney, he focuses his practice on patent prosecution and counseling, opinion work, and patent portfolio strategy in the chemical and biotechnology arts. Dr. Vanik has significant experience working with foreign patent associates to help secure foreign patent rights for U.S. clients. Dr. Vanik also has experience prosecuting patent applications related to biotechnology, plants, chemical compounds, small-molecules, pharmaceutical compositions and antibodies ad proteins.

Prior to joining Baker Donelson, Dr. Vanik worked as an associate for several years in a Washington, D.C., law firm and was also a patent examiner at the United States Patent and Trademark Office. As an examiner, Dr. Vanik's docket encompassed a wide range of technologies including small molecules, pharmaceutical compositions, medical device coatings, rapid and extended release drug delivery formulations, liposomes, tissue engineering compositions, nanoparticles, cosmetics, hair care products, and methods of treating cancer. Additionally, in evaluating patent applications, Dr. Vanik participated in patentability interviews and pre-appeal conferences, conducted prior art searches, and drafted Office actions. Dr. Vanik also has experience examining applications filed under the Patent Cooperation Treaty (PCT).

As a graduate student, Dr. Vanik investigated the biophysical properties of the mad cow disease-related prion protein using a multitude of biophysical techniques to study the molecular basis of the propagation and interspecies transmission of prion disorders. In addition to his work in the lab, Dr. Vanik helped to develop a novel chemistry course entitled "Chemistry and the World."

Admissions

- District of Columbia, 2008
- State of Illinois, 2007
- United State Patent and Trademark Office

Education

- The George Washington University Law School, J.D., 2007
- Case Western Reserve University, Ph.D., 2004, Protein Chemistry
- Washington & Jefferson College, B.A., 1998, Chemistry and Philosophy

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Drew Lowery, Ph. D.

Dr. Lowery is the Group Leader of the Biotechnology & Pharmaceuticals Group at Global Prior Art. Global Prior Art (www.globalpriorart.com) has been helping clients within law firms and companies with their IP search needs for over 25 years. Dr. Lowery has directed hundreds of prior art, FTO, acquisition due diligence and IP landscape analysis projects, and his areas of specialization include: biological signaling networks, therapeutic proteins including modified antibodies and oncology. He received his Ph.D. in Biochemistry from the Massachusetts Institute of Technology where his research focused on intracellular signaling networks and resulted in numerous scientific articles in top tier journals, including Science and Nature.

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David C. Rieveschl concentrates his practice in the areas of securities, corporate, mergers and acquisitions, and banking law. His practice includes structuring public and private sales of equity and debt instruments and advising clients on compliance with federal and state securities laws. In addition, Mr. Rieveschl regularly counsels emerging enterprises on issues affecting legal structure, intellectual property rights and venture capital financing, with particular focus on technology, health care and renewable energy companies. Mr. Rieveschl also represents publicly traded and privately held clients (as buyers and sellers) in complex merger, stock and asset purchase transactions.

Recent Representative Matters

- Advised gaming company in: (1) restructuring of Louisiana subsidiaries through multi-step process of mergers, conversions and liquidations, producing projected Louisiana tax savings of approximately $3 million per year; (2) issuance of $500 million worth of senior notes in connection with corporate refinancing; and (3) amendment of credit facility extending existing facility by $1.5 billion.
- Represented retirement community in connection with $30 million revenue bond issuance by St. Tammany Public Trust Authority to finance construction of new facilities.
- Represented oil and gas exploration company in acquisition of multiple offshore oil leases located in Gulf of Mexico and production payment purchase financing arrangement to fund workovers of existing wells in Gulf of Mexico.
- Represented wine company through negotiation of wine supply agreement and trademark cross licensing agreements with Chilean wine company.
- Represented publicly traded health care company, including its $106 million acquisition of leading competitor and $76 million initial public offering.
- Represented leading global provider of on-demand electronic messaging and transaction services, including its $67 million acquisition of major competitor and $70 million senior convertible debt offering.
- Represented telecommunications holding company, including its $201 million senior convertible debt offering and $81 million acquisition of group of Louisiana based cellular tower companies.
- Guided publicly traded energy company through tax-driven corporate restructuring.

- Counseled specialized supplier of biofuel energy systems engaged in the design, manufacture and construction of biofuel combustion plants for the production of heat or combined heat and power for clients in North America.
- Counseled startup venture engaged in the production and distribution of cellulosic ethanol.
- Advised developer of clean combustion technologies for biosolids and other organic wastes in its offering and sale of up to $42 million of Series B Preferred Stock to group of United States and international investment funds.
- Represented company engaged in the importation, distribution, marketing and sale of wine, including its initial rounds of financing and trademark protection of brands created.
- Guided leading provider of automated wide-area surveillance through its sale to leading provider of energy and environmental solutions, building controls, fire safety and security systems.
- Oversaw bank holding company's $48 million sale to publicly traded strategic acquirer.
- Represented publicly traded bank holding company, including its $23 million acquisition of strategic target.
- Guided publicly traded bank holding company through its going private transaction.
- Represented multiple non-profit educational institutions in Louisiana government bond financing transactions.

Publications & Speaking Engagements

- Organizer and Presenter – Baker Donelson Emerging Company Boot Camp, New Orleans Entrepreneur Week, New Orleans, Louisiana (March 25, 2011)
- Panelist – The Idea Village Entrepreneurship 101 Series, New Orleans, Louisiana (January 5, 2011)
- Organizer and Presenter – Baker Donelson Emerging Company Boot Camp, Baton Rouge and New Orleans, Louisiana (November 16 & 18, 2010)
- Panelist – Technology Issues in Acquisitions, 23rd Annual Technology Law Institute, Institute of Continuing Legal Education in Georgia, Atlanta, Georgia (October 16, 2008)

Professional Honors & Activities

- AV® Preeminent™ Peer Review Rated by Martindale-Hubbell
- Member – Board of Tulane Association of Business Alumni
- Member – Louisiana Technology Council
- Member – Louisiana State Bar Association
- Member – State Bar of Georgia
- Member – Bar Association of the District of Columbia
- Member – New York State Bar Association

- Member – American Bar Association

Civic & Community Activities

- Member – Audubon Nature Institute
- Member – USA Triathlon
- Member – Tulane Association of Business Alumni
- Member – Tulane Law Alumni Association
- Member – Duke Alumni Association and Duke Club of Louisiana
- Member – Lawrenceville Alumni Association

Admissions

- Louisiana, 2003
- Georgia, 2007
- District of Columbia, 1998
- New York, 1998

Education

- Tulane Law School, J.D., *magna cum laude*, 1997
  - Managing Editor, *Tulane Law Review*
- A.B. Freeman School of Business, M.B.A., 1997
- Duke University, B.A., 1991

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Hena Schommer

Hena M. Schommer is a member of Baker Donelson's International Trade & Transactions Group, in the Washington, DC office. The practice focuses on various international trade matters and includes global business compliance, import/export law and sanctions law advising. She began working with Baker Donelson while still in law school in 2009 and graduated with her Juris Doctor from the American University Washington College of Law in 2010. Ms. Schommer completed an academic year abroad studying European and International Business Law in Paris, France. While abroad she competed in the 2010 Willem C. Vis International Commercial Arbitration Moot in Vienna, Austria where she received an Honorable Mention Martin Domke Award Best Individual Oralist In the General Rounds.

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W. Edward Ramage, shareholder in the Firm's Nashville office, concentrates his practice in the areas of patent and intellectual property law and litigation, including the protection and management of intellectual property asset portfolios. He is Chairman of the Firm's Intellectual Property Group.

His patent prosecution experience includes preparing and prosecuting applications for medical devices, healthcare IT systems, computer-enhanced business methods, computer software and hardware systems and networks, computer-based business methods, fabrics, film labels and adhesives, enhanced petroleum recovery, and electronic and mechanical devices. His litigation experience includes copyright, patent, trademark and trade dress litigation in federal and state courts. He is licensed to practice before the U.S. Patent and Trademark Office, and is admitted to the United States Sixth Circuit Court of Appeals and Federal Circuit Court of Appeals.

He graduated from Harvard University *cum laude* with a degree in Geological Sciences, and received his Engineer (Master's) degree from Stanford University, where he studied at the Stanford University Petroleum Research Institute. He was employed as a Petroleum Engineer with Shell Offshore, Inc. in New Orleans, Louisiana for four years before attending the Vanderbilt School of Law. While at Shell Offshore, Inc., he designed and programmed the strategic planning program for calculating the comparative economics and production of all oil and gas reserves for all divisions of the company, and designed and programmed the database program for the monitoring and reporting of wellhead pressures for production platforms in the Gulf of Mexico. He also was employed as a Petroleum Consultant for two years by Warren K. Kourt & Assoc. in Palo Alto, California.

Recent Representative Transactions

- Counsel to international corporation for patent matters.
- Counsel to national bank for Internet security.
- Patent counsel to national financial services company.
- Patent counsel to independent engineering firm designing trusses for space-based applications.
- Patent counsel to international machinery and replacement parts manufacturer.
- Won judgment for national restaurant chain against competitor for trade dress infringement.

Examples of recent issued patents and published applications:

- "Image Exchange Without Full MICR Qualification" (U.S. Pat. No. 7,757,938)
- "Spherically Housed Loudspeaker System" (U.S. Pat. No. 7,796,775)
- "Work Roles Yields Management System and Method" (U.S. Pat. No. 7,822,634)
- "Reciprocal Data File Publishing and Matching System" (U.S. Pat. No. 7,191,176 B2)
- "System and Method for Creating Customer Intimacy With A Brand" (U.S. 2007/0061199 A1)
- "Optical Sensor Based On Surface Electromagnetic Wave Resonance in Photonic Band Gap Materials" (U.S. Pat. No. 7,436,596)
- "Film Label and Coating" (U.S. 2007/0048480 A1)
- "System and Method for Detecting, Analyzing and Controlling Hidden Data Embedded in Computer Files " (U.S. 2006/0174123 A1)
- "System and Method for the Secure Processing of Securities Transactions" (U.S. 2006/0031247 A1)
- "Reusable Microfiber Non-Woven Cleaning Fabric" (U.S. 2006/0014462 A1)
- "System and Method for Tracking Patient Flow" (U.S. 2005/0209886 A1) (RFID tracking system)
- "Apparatus and Method Providing Distributed Access Point Authentication and Access Control with Validation Feedback" (U.S. 2005/0102291 A1)
- "Content Distribution and Incremental Feedback Control Apparatus and Method" (U.S. 2005/0033801 A1)
- "Surgical Instruments and Method for Corneal Reformation" (U.S. Pat. No. 7,153,316)
- "Medicine Cap Timing Apparatus" (U.S. Pat. No. 7,796,472)
- "Intraocular Multifocal Lens" (U.S. Pat. No. 7,144,423)
- "Deployable Truss Beam with Orthogonally-Hinged Folding Diagonals" (U.S. Pat. No. 7,028,442)
- "Electric Solenoid with Adaptable Connectors and Mountings" (U.S. Pat. No. 6,784,772 B1)
- "Electric Generator and Motor Drive System" (U.S. Pat. No. 6,717,281 B1)

Publications & Speaking Engagements

- "Patent Reform's 'Brave New World,'" *The Mississippi Bar* Newsletter, Intellectual Property Section (January 2012)
- "Gene Patents Survive in the United States...For Now," *IP Value 2012* (2012)
- Co-author – "Patent Reform's 'Brave New World,'" *Bio-IT World* (September 19, 2011)
- Co-author – "*Bilski*'s Impact on Medical Method Patents," *Intellectual Asset Management* (July/August 2011)
- "Business Methods Patents Survive... For Now," *IP Value 2011* (2011)
- "Gene Patents Under Attack," *IP Value 2010*, 64 (2010)
- Co-author – "A Total Knockout? Gene Patents Invalidated," *Bio-IT World* (April 2010)

- "The Truth About Business Method Patents," *Intellectual Asset Management* 59 (March/April 2009)
- "The Doctrine of Patent Exhaustion Gets Fresh Legs," *Patents in the USA 2008: A Guide for Japanese Executives* 16 (2008)
- "Patenting Law Basics and Issues," *Intellectual Property Law*, Lorman Education Services Seminar (May 2006)
- "Patent Potpourri," Tenn. Bar Association, Third Annual Intellectual Property Seminar (April 2006)
- "Practical Patenting 101: Avoiding Some Common Pitfalls for the Inventor" (April 2005)
- "Patenting the Franchise," D&S Legal Update (Jan. 2002)
- Panel Member – Tennessee Innovation Conference 2008, 2010 (Tennessee Technology Development Corporation)

Professional Honors & Activities

- Member – American Intellectual Property Lawyer's Association, Member of PCT Issues, Management of IP Assets, and Patent Law Committees
- Member – Intellectual Property Owners Association
- Member – American Bar Association, Section on Litigation, Intellectual Property
- Past Adjunct Professor – Vanderbilt University School of Law, Environmental Law
- Listed in *Mid-South Super Lawyers*, 2007

Admissions

- U.S. Patent and Trademark Office, No. 50,810
- U.S. Court of Appeals for the Federal Circuit
- U.S. Court of Appeals for the Sixth Circuit
- U.S. District Court for the Middle and Eastern Districts of Tennessee
- Tennessee, 1993

Education

- Vanderbilt University Law School, J.D., 1993
- Stanford University, Engineer (Petroleum Engineering and Business Management), 1986. Master's thesis on the comparative economics of steam-flooding vs. in-situ combustion.
- Harvard University, B.A. cum laude (Geological Sciences), 1984. Senior honors thesis on galena lead ore formation in the Viburnum Trend based on the chemical composition of associated dolomite crystals as determined by scanning-electron microscopy.

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Shazi Jiang

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Shazi Jiang, M.D. is an associate in the Firm's Washington, D.C., office and a member of the Intellectual Property Group. Dr. Jiang holds a Doctor of Medicine degree from Vanderbilt University and a J.D. from Vanderbilt School of Law. As a registered patent attorney with life science research experience, Dr. Jiang focuses primarily on biotechnology and chemical matters.

Fluent in Mandarin Chinese, Dr. Jiang is able to counsel both foreign and domestic clients on matters relating to Life Sciences. As a student, Dr. Jiang participated in the Intellectual Property Clinic. She is a published researcher and co-authored an article for the esteemed *British Journal of Hematology*. Some of her research projects include correlating nuclear scans to CT scans in patients with Emphysema (2006); evaluating patient compliance (2005); and evaluating Lupus patients (2004). She holds an undergraduate degree in Molecular and Cellular Biology.

Publications

- Co-author – "Reduction of cell cycle progression in human erythroid progenitor cells treated with tumor necrosis factor alpha occurs with reduced CDK6 and is partially reversed by CDK6 transduction," Dai C, Chung I, Jiang S, Price JO, and Krantz SB, *British Journal of Hematology 121*, 919-927 (2003)

Admissions

- Tennessee, 2010
- PTO No. 66578
- District of Columbia (Pending)

Education

- Vanderbilt University Law School, J.D., 2010
  - Recipient of the Scholastic Excellence Award in Evidence
  - Women's Law Students Association
  - Health Law Society
  - Asian Pacific American Law Student Association
- Vanderbilt University School of Medicine, Doctor of Medicine, 2007
  - Asian Pacific American Medical Student Association

- Vanderbilt University, B.S., Molecular and Cellular Biology, summa cum laude, 2003
  - Phi Beta Kappa
  - National Merit Finalist

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Bryan W. Jones

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Bryan Jones is an associate in the Firm's D.C. office, concentrating his practice in intellectual property and litigation matters. In particular, Mr. Jones has advised clients regarding procurement and enforcement of patents and trademarks in the biotechnological, metallurgical, pharmaceutical, nutraceutical, and crop sciences. Mr. Jones also has experience in commercial and intellectual property litigation in state and federal courts.

Prior to joining Baker Donelson, Mr. Jones was an extern for the Honorable Charles R. Norgle Sr. in the United States District Court for the Northern District of Illinois and was an intern with Liu, Shen and Associates, a private intellectual property firm in Beijing, China. As a law student, Mr. Jones served as an Associate Justice for the John Marshall Moot Court Executive Board, as a Staff Editor for the John Marshall Review of Intellectual Property Law, and as a competitor in the Jessup International Law and the Stetson International Environmental Law moot court competitions. Prior to law school, Mr. Jones worked as a research technician in Dr. Matthew Fenton's lab at Boston University School of Medicine and in Dr. William Klein's lab at Northwestern University. Mr. Jones is a co-author on seven peer-reviewed scientific research articles.

Representative Intellectual Property Matters

- Prepare and assist with the prosecution of patent applications regarding cancer immunotherapeutics, molecular diagnostic assays, herbicidal and insecticidal compounds and compositions, polymer compositions and products, and aluminum alloys and products.
- Patent infringement, validity, and freedom to operate opinions for clients in the biotechnological, pharmaceutical, nutraceutical, and materials science industries.
- Prepare third party ex parte reexamination requests regarding biotechnological patents.
- Represent a patent holder in a pen design patent infringement suit.
- Represent web design and internet advertising company in trademark dispute.
- Trial support in an aerospace products trade secret dispute.

Representative Commercial Litigation Matters

- Breach of contract actions, including patent license/assignment, real estate sales/lease, mortgage, and franchise contracts.
- Trade secret misappropriation and non-competition claims.

- State and federal trademark, unfair competition, and right of publicity litigation.

Other Matters

- Advising a retail client on regulatory matters related to the closing of stores in several states.
- Researching and drafting memoranda opposing a Native American tribe's motion to dismiss based on tribal immunity.

Publications & Speaking Engagements

- Presenter – "Therasense en banc," 2010 Tennessee Intellectual Property Lawyers Association Fall CLE meeting (November 2010)
- Presenter – "Patent Opinions: Validity, Infringement, and Freedom of Operation Practice," 2010 Baker Donelson Symposium, Washington, D.C. (September 2010)
- Presenter – "Fundamentals of Intellectual Property Law," 2010 Invention to Venture Meeting hosted by the University of Tennessee Research Foundation (February 2010)
- Presenter – "Patent Prosecution and the Citation of Companion Applications," 2009 Tennessee Intellectual Property Lawyers Association Fall CLE meeting (November 2009)
- Contributor – 2009 ABA Annual Developments in Franchising Law
- Author – "*Smithkline v. Apotex*: Broadening The Scope Of Inherent Anticipation And Its Impact On The Patentability Of Chemical Structures," 5 The John Marshall Review of Intellectual Property Law 456 (2006)
- Co-First Author – "TLR4, but not TLR2, mediates IFN-beta-induced STAT1alpha/beta-dependent gene expression in macrophages," *Nature Immunology* 2002 Apr;3(4):392-8
- First Author – "Differential roles of Toll-like receptors in the elicitation of proinflammatory responses by macrophages," *Annals of the Rheumatic Diseases* 2001 Nov;60 Suppl 3:iii6-12
- First-Author – "Different Toll-like receptor agonists induce distinct macrophage responses," *Journal of Leukocyte Biology*, 2001 Jun;69(6):1036-44
- Co-Author – "Self-assembly of Abeta(1-42) into globular neurotoxins," *Biochemistry*. 2003 Nov 11;42(44):12749-60
- Co-Author – "TLR2 and TLR4 agonists stimulate unique repertoires of host resistance genes in murine macrophages: interferon-beta-dependent signaling in TLR4-mediated responses," *Journal of Endotoxin Research* 2003;9(3):169-75
- Co-Author – "Toll-like receptors 2 and 4 activate STAT1 serine phosphorylation by distinct mechanisms in macrophages," *Journal of Biological Chemistry*, 2003 Jun 20;278(25):22506-12
- Co-Author – "Differential effects of a Toll-like receptor antagonist on Mycobacterium tuberculosis-induced macrophage responses," *Journal of Immunology* 2001 Mar 15;166(6):4074-82

Professional Honors & Activities

- Member – American Intellectual Property Law Association
- Member – American Bar Association
- Recipient – *Journal of Leukocyte Biology* Dolph Adams Award recipient for the most highly cited research paper over the previous five years (2005)

Admissions

- Tennessee, 2007
- District of Columbia, 2010
- U.S. Patent & Trademark Office, 2010

Education

- The John Marshall Law School, J.D., 2007, Certificate in Intellectual Property Law
- Northwestern University, M.S. Neurobiology and Physiology, 2003
- The Ohio State University, B.S. Molecular Genetics, 1999

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D. Christopher Holly

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Christopher Holly is an associate in Baker Donelson's Washington, D.C., office and is a member of the Firm's Intellectual Property Group. As a registered patent attorney, Dr. Holly focuses his practice on patent prosecution involving matters in the biotechnology and chemical arts.

Prior to entering law school, Dr. Holly's research focused on microbial and phytogenic population and community dynamics. This research was conducted on behalf of the U.S. Department of Agriculture and U.S. Geological Survey Biological Resources Division. These organizations were interested in the development of predictive/quantitative population models that could be used to understand microbial communities, in agricultural settings that were affected by invasive plant species. Utilizing population level data, as well as molecular techniques to characterize the microbial organisms of interest, the investigations led to significant insights that culminated in the publication of several peer-reviewed scientific papers.

Relevant Research Experience

- **Microbiology**: Molecular techniques for identification and quantification of microbes, including: PCR, TRFLP, DGGE, Phylogenetic Analysis of 16S rRNA, Gel Electrophoresis, Electron Microscopy, Microbial Enzyme Assays
- **Molecular Biology**: Nucleic acid amplification techniques, DNA Sequencing, Primers, Genotyping and Bioinformatic Analysis upon genotypic populations
- **Statistical Modeling**: Advanced knowledge in statistical programming and design of multivariate predictive models
- **GIS Computer Programming**: Incorporation of developed mathematical models into a geographic information system, specifically utilizing satellite imagery

Professional Honors & Activities

- Member – American Intellectual Property Law Association (Biotechnology Committee)
- Member – American Bar Association
- Member – Mississippi Bar Association
- Member – Patent and Trademark Office Society
- Member – American Association for the Advancement of Science

- Member – National Eagle Scout Association
- Served as expert scientific reviewer for National Science Foundation, multi-national grant proposal
- Served as expert scientific reviewer for 7 peer-reviewed scientific journal articles

Publications & Speaking Engagements

- Co-author – "Examining local transferability of predictive species distribution models for invasive plants: An example with cogongrass (Imperata cylindrica)," *Invasive Plant Science and Management* (2011)
- Author – "The Book of Wisdom: How to Bring a Metaphorical Flourish Into the Realm of Economic Reality by Adopting a Market Reconstruction Requirement in the Calculation of a Reasonable Royalty," 92 *J. Pat. & Trademark Off. Soc'y* 156 (2010)
- Lead Author – "Effect of an invasive grass on ambient rates of decomposition and microbial community structure: A search for causality," 11 *Biological Invasions* 1855 (2009)
- Lead Author – "Effects of intraspecific seedling density, soil type, and light availability upon growth and biomass allocation in cogongrass (*Imperata cylindrica*)," *Weed Technology*, 2007
- Lead Author – "Characterization and quantitative assessment of interspecific and intraspecific penetration of belowground vegetation by cogongrass (*Imperata cylindrica* (L.) Beauv.) rhizomes," *Weed Biology and Management*, 2006

Admissions

- Tennessee, 2011
- Mississippi, 2011
- U.S. Patent and Trademark Office, No. 67,971
- U.S. Court of Appeals for the Fifth Circuit, 2011
- U.S. District Court for the Northern and Southern Districts of Mississippi, 2011

Education

- University of Mississippi School of Law, J.D., magna cum laude, 2011
    - *Mississippi Law Journal*
    - *Journal of Space Law*
    - Judge John A. Travis Memorial Scholarship Recipient
    - Dean's Leadership Council
    - Phi Delta Phi Legal Honorary
    - Received Outstanding Student Award in: Antitrust; Intersections of Antitrust and Intellectual Property; White Collar Crime
    - Copeland, Cook, Taylor & Bush Appellate Advocacy Competition: 1st Place (1/163)

- Mississippi State University, Doctor of Philosophy, Biological Sciences, 2008
    - Doctoral Research Associate of the Year Award, Mississippi State University, 2008 (Chosen from among the entire Ph.D. student population at MSU)
- Millsaps College, B.S., Biology, 2004
    - Chemistry Minor
    - Curator of the James Observatory
    - Electron Microscopy Student Researcher

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C.G. Moore is a registered patent attorney in the Firm's Mandeville office. Dr. Moore concentrates his practice on intellectual property matters relating to biotechnology, chemistry, and pharmaceuticals, with particular focus on molecular and cellular biology, small molecule chemistry, neurobiology, drug delivery and medical devices.

In addition to the preparation and prosecution of patent applications, Dr. Moore also has experience with reexamination proceedings, appeals to the Board of Patent Appeals and Interferences, managing patent portfolios, drafting patent licenses and freedom-to-operate opinions, performing due diligence in connection with public financings and acquisitions and litigation involving patents and trademarks.

Dr. Moore gained significant research experience in the life sciences through his work as a research assistant at the Oregon Health Sciences University and later at the Massachusetts General Hospital. He also acquired first-hand experience with the biotechnology industry while working with the New England Organ Bank and the Transplant Resource Center of Maryland.

As a Ph.D. candidate at the Johns Hopkins University School of Medicine, Dr. Moore's thesis research focused on the regulation of glutamate receptors and their interaction with Homer proteins, demonstrating a role for coordinated phosphorylation and isomerization.

During law school, Dr. Moore was an intern and patent agent with the Tulane University Office of Technology Transfer and Business Development, where he prepared patent applications, participated in patent licensing transactions and developed marketing strategies.

Representative Technologies

- Biotechnology / Chemical / Pharmaceutical – small molecule and protein pharmaceutical compounds; DNA regulatory elements; liposomes; antisense DNA vaccines; plasmid expression vectors; insecticides; synthetic polymers
- Medical – suture anchor assemblies; vascular stents; remote endarterectomy devices; stent placement and manipulation devices; medication therapy management and quality assurance methods

Selected Pending Patent Applications

- Tuned Synthetic Dendrimer Calibrants for Mass Spectrometry (International Pub. No. WO/2010/091109)

- Stimulus-Responsive Apta-Chelamers (Int'l Pub. No. WO/2010/006238)
- Thermoresponsive Microparticle Composite Hydrogels for Electrophoresis (U.S. Patent Pub. No. 2009/0127116)
- System for Pulling Out Regulatory Elements In vitro (U.S. Patent Pub. No. 2008/0248958)
- System for Pulling Out Regulatory Elements using Yeast (U.S. Patent Pub. No. 2008/0248467)
- Polyplex Gene Delivery Vectors (not yet published)
- OMV Vaccine Against Burkholderia Infections (not yet published)
- Mesenchymal Stem Cells and Related Therapies (not yet published)
- Fungicidal Compositions and Methods of Use (not yet published)
- Organogenic Transformation of Immature Soybean Embryonic Tips (not yet published)

Publications & Speaking Engagements

- Panelist – "Intellectual Property & Technology Transfer Career Panel," Johns Hopkins University, Professional Development Office Seminar (October 2008)
- Author – "Generic Biologic Drugs: What's in a Name?" *5 The SciTech Lawyer 16* (Fall 2008)
- Author – "Federal Circuit: No § 271(e)(1) Safe Harbor for Patented Inventions Not Regulated by FDA," *6 Health Lawyers Weekly 3* (August 22, 2008)
- Author – "Killing the Bayh-Dole Act's Golden Goose," 8 *Tul. J. Tech. & Intell. Prop.* 151 (2006)
- Author – "Recent Developments in Intellectual Property Law," 52 *LA. B.J.* 294 (2004)

Professional Honors & Activities

- Member – American Bar Association, Member of Science & Technology Law, and Intellectual Property Sections
- Member – Louisiana State Bar Association, Member of Intellectual Property Section
- Member – American Intellectual Property Law Association, Member of Biotechnology, Patent Law, and Emerging Technologies Committees
- Member – Licensing Executives Society, Member of Nanotechnology, and Diagnostics, Genomics & Research Tools Committees

Admissions

- U.S. Patent and Trademark Office, Reg. No. 53,345
- U.S. Court of Appeals for the Federal Circuit
- U.S. Court of Appeals for the Fifth Circuit
- U.S. District Courts for the Eastern, Middle, and Northern Districts of Louisiana
- Louisiana, 2006

Education

- Tulane University, J.D., 2006
- Johns Hopkins University School of Medicine, Ph.D. (Neuroscience), 2004. Thesis: Regulation of Group I Metabotropic Glutamate Receptor Function and Homer Interaction by Phosphorylation of the Homer Ligand
- Portland State University, B.S. (Biology), 1995
- Reed College, B.A. (Chemistry), 1990. Thesis: Building a better backbonder: ligation of Mo^0 by methylpyrazine using molybdenum hexacarbonyl and methylpyrazinium triflate

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Micheline Kelly Johnson, a registered patent attorney and of counsel in the Chattanooga office, concentrates her practice in intellectual property. Ms. Johnson's practice leads the Firm in trademark portfolio management with responsibility for over 1,100 U.S. and international trademark applications and registrations, helping propel Baker Donelson to the number 58 ranking on the "Top 100 Trademark Firms" as noted in the May 2010 issue of *Intellectual Property Today*. Ms. Johnson has obtained trademark protection for both product configurations and market-leading brands, and has negotiated and structured critical international co-existence agreements designed to protect brand strength while embracing business opportunities.

Ms. Johnson assists clients in identifying, protecting, and capitalizing on intellectual property assets. She also performs due diligence evaluations of portfolios in connection with public financings and acquisitions and counsels clients in transactional matters involving intellectual property, including preparing transactional documents for license agreements, joint ventures, mergers and acquisitions, and divestitures. Ms. Johnson's portfolio management includes enforcing clients' intellectual property rights in federal courts and before the Trademark Trial and Appeal Board of the United States Patent and Trademark Office.

Ms. Johnson has prepared and prosecuted domestic and international patents relating to a range of technologies, including chemicals, manufacturing equipment, toys, computer-based business methods, and general mechanics. In addition, Ms. Johnson evaluates patents and drafts license agreements, freedom-to-operate opinions, validity/invalidity opinions, patentability opinions, and non-infringement opinions.

Ms. Johnson also has experience in copyright protection and enforcement, and Internet, eCommerce, and domain name matters. She has served as an expert in patent litigation and is the former Chair of the Firm's Intellectual Property Group.

Ms. Johnson holds the highest rating for ability and ethics, the AV® rating from Martindale-Hubbell, based on anonymous surveys of lawyers and judges.

Professional Honors & Activities

- AV® Preeminent™ Peer Review Rated by Martindale-Hubbell
- Listed in *The Best Lawyers in America*® in Trademark Law, 2012
- Volunteer – Pro Bono Attorney in the Chattanooga legal aid program
- Volunteer – Pro Bono Attorney in the Atlanta legal aid program

- Member – Tennessee (Patent, Trademark and Copyright Sections) Bar Association
- Member – Georgia (Patent, Trademark and Copyright Sections) Bar Association
- Member – American Bar Association
- Member – International Trademark Association
- Member – Fédération International des Conseils en Propriété Industrielle (FICPI)
- Member – Association Internationale pour la Protection de la Propriété Intellectuelle (AIPPI)
- Member – American Chemical Society

Community Leadership & Activities

- Past Board Member – The Junior League of Chattanooga
- Past Chairman – Corporate Partnership for Lookout Mountain Elementary School
- Past Board Member – St. Jude Home and School Association
- Past Member – Girls' Preparatory School Auction Committee

Admissions

- Tennessee, 1989
- District of Columbia, 1988
- U.S. Patent and Trademark Office, 1988
- Georgia, 1986

Education

- Vanderbilt University, J.D., 1986
  - Student Writing Editor – *Vanderbilt Journal of Transnational Law*
- Vanderbilt University, M.B.A. (Finance), 1986
  - Owen Merit Scholar
- Spring Hill College, B.S. (Chemistry), 1982, cum laude
  - Miller-LeJeune Memorial Scholar

BAKER DONELSON
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Laine Glisson Oliver

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Laine Glisson is a senior public policy advisor in the Firm's Washington, D.C., office, where she serves as one of Baker Donelson's chief policy strategists. She is an experienced public policy advisor who has counseled members of Congress, mayors and executives for more than 15 years in Washington, D.C.

Ms. Glisson's clients benefit from her ability to approach policies in a bi-partisan fashion with moderate Democrats and Republicans in both chambers of Congress. She has helped clients reach their legislative goals in a number of different areas, including recent wins on prevention and wellness issues in the Patient Protection and Affordability Act of 2010; in the area of energy and the environment on water issues, and specifically for the City of New Orleans in the aftermath of Hurricane Katrina. Ms. Glisson has significant experience building brand recognition for clients on the Hill and has worked with a number of Caucuses to advance legislative interests, including the Congressional Black Caucus, the Alzheimer's Caucus, Third Way, and the Congressional Water Caucus. She has also represented clients in the telecommunications and satellite industries, having worked for NTCA, the nation's largest rural telecommunications trade association.

Ms. Glisson spent five years on Capitol Hill with Senator John Breaux (D-La.) where she served as a Press Secretary handling issues related to the Senate Finance Committee, The Commerce Committee, The Special Committee on Aging and during the National Bipartisan Commission on the Future of Medicare. She also wrote and produced his monthly television show "Jambalaya." Ms. Glisson most recently served as a Senior Vice President at Dutko Worldwide, where she worked with numerous Fortune 500 Companies, trade associations, municipalities and coalitions on legislative strategy, messaging and policy.

Ms. Glisson was a media strategist for Olympic athlete Carl Lewis and the Santa Monica Track Club during the 1994 Goodwill Games in Russia. She has appeared as a guest on the FOX News Channel as a Democratic Strategist, is frequently quoted in other Washington, D.C., media outlets, and is often used inside the Beltway as a resource for political opinions.

Education

- Louisiana State University, B.S., 1991

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JC Sandberg

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JC Sandberg has an in-depth understanding of the Federal legislative process and a demonstrated ability to complete complicated legislative initiatives involving hundreds of competing constituencies.

While serving as counsel to the U.S. Senate Committee on Environment and Public Works from 2001 to 2006, Mr. Sandberg was deeply involved in every facet of the legislative process coordinating initiatives among various Senate committees including Banking, Commerce, Finance, Appropriations, and Budget. As one of the lead negotiators for members of the Senate, he played a significant role in the passage of the bipartisan $286 billion reauthorization of the Transportation Equity Act for the 21st Century (surface transportation bill). During the surface transportation reauthorization, Mr. Sandberg also advised the Senate Democratic Leader on reauthorization policy and strategy.

During his Senate tenure, Mr. Sandberg also guided legislation through the Senate to aid the relief and recovery efforts in New York City and Washington, D.C., following the September 11th terrorist attacks and organized numerous oversight hearings on Federal disaster response, creation of the Department of Homeland Security, and Federal transportation policy. He also conducted oversight of the U.S. Environmental Protection Agency's regional enforcement practices.

In 2005, the *National Journal* recognized Mr. Sandberg's work, naming him one of the "Hill 100" key congressional staff members.

Publications & Speaking Engagements

- American Association of State Highway and Transportation Officials (AASHTO) Annual Meeting (2003, 2005, 2006)
- International Bridge, Tunnel and Turnpike Association Annual Meeting (2006)
- U.S. Conference of Mayors Annual Conference (2005)
- National League of Cities Conference (2003, 2004, 2005)
- Congressional Black Caucus Foundation's Annual Legislative Conference (2005)
- U.S. Economic Development Administration National Forum (2001, 2002)

Professional Honors & Activities

- Fellow – John C. Stennis Center for Public Service, 109th Congress
- Named one of *National* Journal's "Hill 100" Key Congressional Staff Members (2005)

- Recipient – University of Arizona College of Law Public Service Award (2000)

Admissions

- District of Columbia, 2008
- California, 2000

Education

- University of Arizona, J.D., 2000
- Brigham Young University, B.S., 1997

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Samuel F. Miller

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Sam Miller, a shareholder in the firm's Nashville office, protects and defends businesses and individuals involved in "bet the company" intellectual property and technology disputes. Mr. Miller has successfully served as lead counsel for a wide range of clients from individuals to small businesses to Fortune 500 companies in copyright, trademark, trade dress, patent, right of publicity, false advertising, internet defamation and technology-related litigation.

He has extensive experience in state and federal courts throughout Tennessee and the United States, including recent cases in the Middle, Western and Eastern Districts of Tennessee; the Southern District of New York; the Northern District of Georgia; the District of Colorado; Central and Northern Districts of California; the Eastern District of Texas; and the District of Idaho. Mr. Miller has particular experience in prosecuting and defending against motions for temporary restraining orders and preliminary injunctions in intellectual property and technology cases.

He has experience in arbitration proceedings involving domain name disputes and Trademark Trial and Appeal Board opposition and cancellation proceedings.

In addition to traditional intellectual property matters, Mr. Miller has represented music artists in right of publicity cases and royalty disputes, including the first case in which the Tennessee Court of Appeals held that venue in an action to collect unpaid writer's royalties is proper where the songwriter resides. He also has represented individuals who have been defamed on websites or postings on the internet.

Mr. Miller was named a Mid-South Rising Star in Intellectual Property in 2008 and Intellectual Property Litigation in 2009 by *Super Lawyers* magazine.

Mr. Miller is the Chair of the Intellectual Property Section of the Tennessee Bar Association for 2011 – 2012. He previously served as the Chair of the Intellectual Property Section of the Tennessee Bar Association from 2009 – 2010; the Vice-chair of the Intellectual Property Section of the Tennessee Bar Association and on the governing board of the Tennessee Intellectual Property Law Association. He was an adjunct professor in intellectual property at the Cecil C. Humphreys School of Law at the University of Memphis. Mr. Miller is a member of the Sedona Conference Working Group on Electronic Document Retention and Production.

Representative Matters

Trademark/Trade Dress/False Advertising

- Represented publicly-traded pharmaceutical company in false advertising and trademark infringement case valued at hundreds of millions of dollars.
- Obtained summary judgment in favor of nationwide retailer in trademark and cybersquatting action before the United Stated District Court for the Central District of California in Los Angeles.
- Awarded dismissal of trade dress declaratory judgment lawsuit in United States District Court for the District of Colorado on behalf of medical device company.
- Obtained a settlement on behalf of Nashville based seller of specialty pens against large distributor of specialty products in trademark infringement action
- Defeated motion for summary judgment in TTAB case involving allegations of trademark abandonment.
- Obtained successful resolution of trademark infringement and unfair competition lawsuit involving well-known identity theft prevention companies.
- Procured two cancellations of trademark registrations before the Trademark Trial and Appeal Board on behalf of national supplier of medical products to physician practices.
- Successfully resolved trademark infringement dispute in favor of large local music festival against infringing adult entertainment establishment.
- Obtained reinstatement of trademark registration that was wrongfully cancelled on behalf of large religious organization.
- Represented manufacturer of high-end appliances in case involving false advertising claims by competitor.
- Resolved trademark and trade dress infringement lawsuit involving Memphis-based restaurant versus two California cocktail lounges.
- In February 2008, settled two well-publicized trademark and unfair competition lawsuits between a historic Memphis enterprise and a record label based in Nashville.
- Obtained dismissal for well-recognized motorcycle frame designer in trade dress infringement action before the United States District Court for the Central District of California in Los Angeles.

Copyright

- Obtained motion for judgment on the pleadings that reduced potential statutory damages award against client by nearly $100 million.
- Reached positive settlement for developer accused of copyright infringement based on website design and content.
- Represented manufacturer accused of infringement in which plaintiff sought damages in excess of $150 million.
- Represents owner of distinctive design for cupcake liners in claims for infringement.
- Obtained reversal of trial court dismissal before the Tennessee Court of Appeals in which the Court held for the first time that venue in an action to collect unpaid writer's royalties is proper where the songwriter resides.

- On behalf of high-end appliance manufacturer, obtained settlement in which alleged infringer agreed to remove certain webpage from its website.

Patent

- Obtained settlement in design patent case that enjoined distributor, reseller, and importer from making, using, selling, offering for sale and importing products that are substantially the same as the claimed ornamental designs.
- Represented numerous patent owners and defendants in patent infringement lawsuits in courts throughout the United States involving mechanical, chemical, business method and software-related technologies.
- Represented multinational corporation regarding contract dispute over whether sufficient scope of patent protection was obtained in Japan.

Publications & Speaking Engagements

- Peer Reviewer – "IP Issue for Start-Up Companies," *Intellectual Property Deskbook for the Business Lawyer*, 3d edition
- Contributing Author – "Right of Publicity Survey," *Practical Law Company*
- Co-presenter – "Damages and the Calculation of Damages in Intellectual Property Cases," Intellectual Property Section, Nashville Bar Association (November 30, 2011)
- Co-presenter – "Intellectual Property and Political Campaigns," Tennessee Intellectual Property Law Association, Nashville, Tennessee (November 11, 2011)
- Presenter – "Are You Sure You Own the Copyrights in Your Code?" Suffolk University Law School podcast (August 2011)
- Author – "Are You Sure You Own the Copyrights in Your Code?" *BakerTech* newsletter (August 10, 2011)
- Presenter – "Intellectual Property in Advertising and Marketing Series," Baker Donelson Seminar (Summer 2011)
- Presenter – "Ethics for IP Lawyers - 2011," Tennessee Bar Association's Intellectual Property Forum (March 4, 2011)
- Presenter – "Trademark, Copyright and Labor and Employment Basics for Breweries and Distilleries," Baker Donelson seminar (March 3, 2011)
- Author – "Purchasing Internet Keywords – Buyer Beware," Baker Donelson's *Hospitalitas* newsletter, 2010 Issue 2 (April 2010)
- Presenter – "Intellectual Property in the Digital Age: What is it and how do you protect it?" PodCamp, Nashville, TN (March 6, 2010)
- Presenter – "Intellectual Property Law," TECworks FastTrac Program (October 22, 2009)
- Adjunct professor – Intellectual Property Law, University of Memphis Cecil C. Humphreys School of Law (Fall 2009)
- Guest Lecturer – "Introduction of Copyright Law" for survey course of "Intellectual Property Law" for the University of Mississippi School of Law (October 31, 2008)

- Author – "How to Stop Others from Using Your Business's Trademarks in a Website Address," Tennessee Chamber of Commerce & Industry's Business Insider (August 2008)
- Presenter – "Discovery Documents, Trial Exhibits and the Copyright Act" for the Tennessee Intellectual Property Law Association in Nashville, Tennessee (May 2, 2008)
- Presenter – "The TTAB Rule Changes and Other Recent Changes in Trademark Law" for the Tennessee Bar Association's Intellectual Property Forum (April 11, 2008)
- Presenter – "Patent Law," for the National Business Institute in Memphis, Tennessee (December 18, 2007)
- Presenter – "Recent Development in Trademark Law, including the New TTAB Rules," for the Tennessee Intellectual Property Law Association in Nashville, Tennessee (November 9, 2007)
- Presenter – "Ten Things Every Educator Should Know About the Copyright Act," for St. Agnes High School, Memphis, Tennessee (April 4, 2007)
- Presenter – "The Spy in Your Cell Phone," *Financial Institutions Advisor*, Vol. 2 No. 2 (June 2004)
- Presenter – "Is International Filing Best for Your Trademark," *Innovation*, Vol. 3 No. 4 (December 2003)
- Presenter – "Prescriptive Jurisdiction over Internet Activity: The Need to Define and Establish the Boundaries of Cyberliberty," *10 Indiana Journal of Global Legal Studies*, Issue 2 (Summer 2003)

Professional Honors & Activities

- Listed in *Mid-South Rising Stars*, 2008 and 2009
- Member – Tennessee Bar Association (Chair, Intellectual Property Section, 2011 – 2012; Chair, Intellectual Property Section, 2009 – 2010; Vice-Chair, Intellectual Property Section, 2008 – 2009)
- Member – Tennessee Intellectual Property Law Association (Board member, 2007 – 2009)
- Board Member – Woodbine Community Organization, a non-profit organization that provides affordable housing and other services to the Middle Tennessee community
- Member – American Intellectual Property Law Association
- Member – Sedona Conference Working Group on Electronic Document Retention and Production (2011 – present)
- Excellence for the Future Award from the Center for Computer-Assisted Legal Instruction for achievement in the seminar "Patents and Emerging Technologies"

Admissions

- Tennessee
- U.S. District Court for the Middle, Eastern and Western Districts of Tennessee

- U.S. Court of Appeals, Sixth Circuit
- U.S. District Court for the District of Colorado
- U.S. District Court for the Eastern District of Texas

Education

- Indiana University School of Law, J.D., 2003, cum laude
- USD Institute on International and Comparative Law at Trinity College, Dublin, Ireland, 2002
- Xavier University, B.A., 2000, cum laude

BAKER DONELSON
BEARMAN, CALDWELL & BERKOWITZ, PC

Susan Elizabeth McBee

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Susan McBee, shareholder in Baker Donelson's Washington, D.C., office, is a member of the Firm's Intellectual Property Group and Chair of the Life Sciences Intellectual Property Team. As a registered patent attorney, Ms. McBee concentrates her practice in the field of chemistry and biochemistry. She has over 15 years of experience in patent and trademark portfolio management for large Fortune 500 companies. She is often involved in IP due diligence during acquisitions and licensing negotiations involving her clients.

Ms. McBee has represented clients in many chemical, biochemical and engineering fields including agricultural chemistry, polymer chemistry, fermentation and extraction of proteins, food additives and processes, small molecule chemistry, medical devices, metallurgy, packaging materials, electronic materials and associated methods of manufacture and use. She also has extensive experience with both ex parte and inter partes reexamination proceedings at the U.S. Patent and Trademark Office (USPTO) both as representing patentees as well as third party requestors.

Before becoming a patent attorney, Ms. McBee owned a patent search company and worked as a patent examiner at the USPTO in the field of polymer chemistry/light sensitive materials.

Recent Publications

- Co-author – "*Bilski*'s Impact on Medical Method Patents," *Intellectual Asset Management* (July/August 2011)

Professional Honors & Activities

- Member – Frederick County, Maryland and American Bar Associations
- Member – American Intellectual Property Lawyers Association (AIPLA)

Admissions

- District of Columbia, 1998
- U.S. Court of Appeals Federal Circuit, 1997
- Maryland, 1996
- USPTO, 1994

Education

- George Mason University School of Law, J.D., 1996 with high honors

- Alderson-Broaddus College, B.S. chemistry, 1987, *cum laude*

BAKER DONELSON
BEARMAN, CALDWELL & BERKOWITZ, PC

David W. Woodward

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- Mr. Woodward is a Shareholder in the Washington, D.C., office and a member of the Firm's Intellectual Property Group. He has over two decades of experience as a patent practitioner, and has successfully represented clients before the Patent and Trademark Office in complex prosecution, reexamination, reissue and appeal matters. Prior to joining Baker Donelson, Mr. Woodward was a partner in the Intellectual Property Litigation Group at Sidley Austin LLP. He also served as a Patent Examiner for the U.S. Patent and Trademark Office in the chemical and polymer arts from 1986 to 1991.

- Mr. Woodward has extensive experience in representing pharmaceutical, chemical and biotech companies in all areas of patent practice, from procurement to litigation to appeal. He has counseled clients on patent drafting and prosecution, validity, infringement, clearance, due diligence, patent portfolio management and strategy. He is an experienced patent litigator, including in complex Hatch Waxman litigation. Mr. Woodward also has particular experience in performing intellectual property audits in several contexts, including litigation preparation, product investments or approvals, licensing, acquisitions and other significant deals.

- Mr. Woodward has degrees in chemistry and chemical engineering and extensive experience in pharmaceuticals, small molecules, polymers, formulations, organic and inorganic chemistry, chemical processing, chemical engineering and biotechnology, including antibodies.

Education

- George Washington University Law School, first in class, J.D., 1992
- Virginia Tech, B.S. Chemical Engineering and Chemistry, 1986

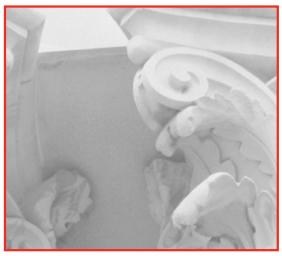
Admissions and Certifications

- District of Columbia, 1994
- Virginia, 1992
- U.S. Court of Appeals, D.C, Circuit, 1994
- U.S. Court of Appeals, 4th Circuit, 1992
- U.S. Court of Appeals, Federal Circuit, 1992
- USPTO, 1992 (Reg. No. 35,020)

Professional Honors & Activities

- Member – American Bar Association, Intellectual Property Section
- American Chemical Society
- Patent and Trademark Office Society
- Member – American Intellectual Property Lawyers Association (AIPLA)

BAKER DONELSON'S
FIRM PROFILE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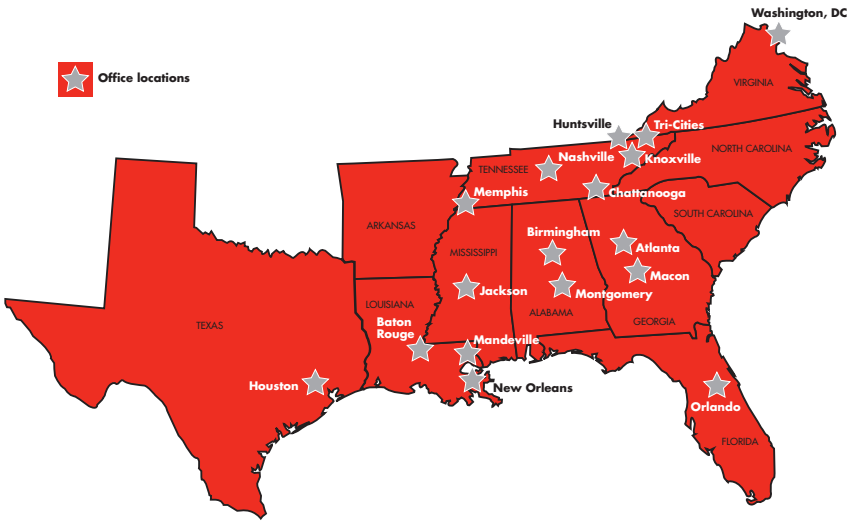
BAKER DONELSON

Since our beginnings in 1888, Baker Donelson has built a reputation for achieving results for our clients on a wide range of legal matters. While providing legal services is our focus, it is how we deliver them that sets us apart. Our goal is to provide clients with more than what they have come to expect from a law firm.

Baker Donelson commits to a deep understanding of a client's business, to enable us to anticipate clients' needs and assist in their decision making processes. Because we offer consistent, knowledgeable guidance based on their specific goals and objectives, clients view us as a valued business partner. This allows them to focus on the growth and success of their business, confident their legal issues will be handled by an attentive, responsive team.

Our unique approach to providing legal services is enabled by our extensive support structure. As the 73rd largest law firm in the U.S., Baker Donelson gives clients access to a team of more than 600 attorneys and public policy advisors representing more than 30 practice areas, all seamlessly connected across 18 offices to serve virtually any legal need. Clients receive informed guidance from experienced, multi-disciplined industry and client service teams. Our diversity and women's initiatives ensure diversity in our people, perspectives and experiences. Technology helps us operate more effectively and efficiently by providing instant access to client-specific information and other key resources.



States of Licensure

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New Jersey
New Mexico
New York
North Carolina
Ohio
Pennsylvania
Rhode Island
South Carolina
Tennessee
Texas
Virginia
West Virginia
Washington
Wisconsin

Firm Recognition

- Named as 73rd largest law firm by *National Law Journal* in 2011.
- Ranked by FORTUNE as one of the "100 Best Companies to Work For" in 2010, 2011 and 2012.
- 182 Tier 1 metropolitan rankings in 2011 *U.S. News – Best Lawyers* "Best Law Firms" list.
- Consistently ranked in the "Top 100 U.S. Law Firms For Diversity" by *Multicultural Law* magazine since 2005.
- Ranked in the "Top 100 Law Firms For Women" since 2008 by *Multicultural Law* magazine.
- Since 2006, listed as a "Go-To Law Firm" in the *Directory of In-House Law Departments* of the Top 500 Companies produced by *Corporate Counsel* and American Lawyer Media.
- 69 attorneys in *Chambers USA: America's Leading Business Lawyers* in 2011.
- 196 attorneys in *Best Lawyers In America*® in 2012 edition. Based upon total number of attorneys listed, we rank first in the nation in the areas of Banking and Finance Law, Business Organizations, Closely Held Companies and Family Businesses Law, Commercial Finance Law, Commercial Transactions/UCC Law, Mass Tort Litigation/Class Actions, Personal Injury Litigation, Privacy and Data Security Law, Product Liability Litigation, Medical Malpractice Law and Transportation Law.
- 81 attorneys in *Mid-South Super Lawyers* and 23 attorneys in *Mid-South Rising Stars* – covering Arkansas, Mississippi and Tennessee; 17 attorneys in *Louisiana Super Lawyers*; 13 attorneys in *Alabama Super Lawyers* and 7 attorneys in *Alabama Rising Stars*; 7 attorneys in *Georgia Super Lawyers*; 7 attorneys in *Georgia Rising Stars*; 2 attorneys in *Florida Super Lawyers*; and 1 attorney in *Texas Super Lawyers* (all 2011 lists).
- Ranked in Tier 1 nationally in transportation Law in 2011 *U.S. News – Best Lawyers* "Best Law Firms" list.
- Ranked as one of the top ten Labor and Employment Litigation firms in the nation by *Employment Law 360* (2006, 2007).
- Ranked among the top bond counsel firms in Mississippi by *The Bond Buyer* (2007, 2008).
- Ranked by *Modern Healthcare* as the fifth largest health law practice in the U.S. (2011).
- Named by *Health Lawyers News* (June 2009) as one of the top ten health law practices in the nation.
- Named by *Nightingale's Healthcare News* (May 2006) as one of the nation's largest health care law practices.
- Selected by *Chambers USA: America's Leading Business Lawyers* (2010) as one of the nation's leading health law practices.
- Ranked by *Intellectual Property Today* since 2007 as one of the top 100 trademark firms in the country.
- Named by *Benchmark: Litigation* (2009) as a Recommended Firm in Louisiana, Mississippi and Tennessee.
- Ranked by FORTUNE as one of the top ten public policy firms in Washington, D.C. in its most recent survey of this kind.

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BAKER DONELSON'S
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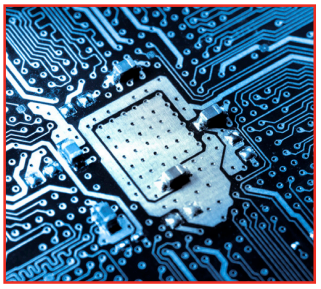


BAKER DONELSON
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W. Edward Ramage is chairman of the Firm's Intellectual Property Group. His experience includes the drafting of patent applications for medical devices, health care IT, and health care related business methods and software and laboratory equipment. Prior to his legal career, Mr. Ramage received his law degree from Vanderbilt University Law School, graduated from Harvard University *cum laude* with a degree in Geological Sciences, and received his Engineer (Master's) degree from Stanford University, where he studied at the Stanford University Petroleum Research Institute.

Susan McBee, chair of the Life Sciences Intelletual Property Group, is a former examiner at the U.S. Patent and Trademark Office and has over 20 years of experience in assisting clients in all facets of IP concerns, particularly in the fields of chemistry, biochemistry, pharmaceuticals and material science. Ms. McBee's experience includes patent prosecution for global Fortune 500 companies, conducting training seminars in intellectual property law, and assisting clients in due diligence reviews for acquisitions or licensing. Ms. McBee has a B.S. in Chemistry and received her J.D. from George Mason University School of Law, graduating with honors.

David Woodward served as a former Patent Examiner for the U.S. Patent and Trademark Office in the chemical and polymer arts and has over two decades of experience as a patent practitioner. He has extensive experience in representing pharmaceutical, chemical, and biotechnology companies in all areas of patent practice, from procurement to experienced patent litigation, including in complex Hatch-Waxman litigation. Mr. Woodward also has particular experience in performing intellectual property audits. Mr. Woodward graduated from Virginia Tech and has degrees in chemistry and chemical engineering and extensive experience in pharmaceuticals, small molecules, polymers, formulations, organic and inorganic chemistry, chemical processing, chemical engineering, and biotechnology, including antibodies. He graduated first in his law school class at George Washington in 1992.

C.G. Moore, Ph.D., has five years of patent prosecution and IP counseling experience, and concentrates his practice on matters relating to biotechnology, chemistry, pharmaceuticals and medical devices. Dr. Moore's experience includes preparing and prosecuting patent applications, managing patent portfolios, drafting license agreements and freedom-to-operate opinions, performing due diligence in connection with public financings and acquisitions, litigation involving trademarks and patents, and reexamination proceedings before the United States Patent and Trademark Office. Dr. Moore received his Ph.D. in neuroscience from the Johns Hopkins University of Medicine and his J.D. from Tulane University.

David L. Vanik, Ph.D., is a former examiner at the U.S. Patent and Trademark Office and has significant experience working with foreign patent associates to help secure foreign patent rights for U.S. clients. Dr. Vanik focuses his practice on patent prosecution and counseling, opinion work, and patent portfolio strategy in the chemical and biotechnology arts. Dr. Vanik has a Ph.D. in Protein Chemistry and received his J.D. from George Washington University Law School.

Bryan W. Jones is a published research technician who has assisted with the preparation and prosecution of biotechnological and polymer science-related patent applications. He has an educational background in life sciences, with a M.S. in Neurobiology and Physiology and a B.S. in Molecular Genetics. Mr. Jones is a graduate of the John Marshall Law School and holds a Certificate in Intellectual Property Law.

Shazi Jiang, M.D. is an associate in the Firm's Nashville office and a member of the Intellectual Property Group. Dr. Jiang holds a Doctor of Medicine degree from Vanderbilt University and a J.D. from Vanderbilt School of Law. As a registered patent attorney with life science research experience, Dr. Jiang focuses primarily on biotechnology and chemical matters.

Mridula Pottathil, Ph.D. is a registered patent agent and concentrates her practice in the field of biotech and ecotech. She has five years of experience in patent and trademark portfolio management for start-up to mid-size companies. Dr. Pottathil has unique experience with IP analysis, strategy and management in entrepreneurial environments. Before becoming a patent agent, Mridula Pottathil completed her doctoral thesis in microbiology from the University of California, Los Angeles.

Christopher Holly, Ph.D. is an associate in the Firm's Washington, D.C., office. He is a member of the Intellectual Property Group, where he concentrates his practice in biotechnology patent prosecution. Prior to entering law school, Dr. Holly's research focused on microbial and phytogenic population dynamics on behalf of the U.S. Department of Agriculture and U.S. Geological Survey Biological Resources Division. Dr. Holly holds a Ph.D. in Biological Sciences from Mississippi State University and graduated magna cum laude from The University of Mississippi School of Law.

Richard E. L. Henderson, Ph.D., has nearly thirty years of experience as a corporate patent practitioner in chemical, agrochemical, pharmaceutical, and polymer technologies. Prior to joining Baker Donelson, he was patent counsel for Bayer Corporation's Industrial Chemicals Division and senior patent counsel and head of the patent group at Bayer CropScience LP. He previously was a patent agent and patent attorney with multinational pharmaceutical companies. Dr. Henderson has significant experience in patent prosecution; the preparation and negotiation of agreements, including license, consulting, and secrecy agreements; and other intellectual property issues, such as patentability, validity, and infringement opinions. An honors graduate of the Chicago-Kent College of Law, Dr. Henderson has a B.S. in Chemistry from the University of North Carolina, Chapel Hill, and a Ph.D. in Organic Chemistry from University of Illinois, Urbana-Champaign.

Selected Subject Matter Areas

Biotechnology/Chemistry/Pharma/ Food & Cosmetic

- Antibodies
- Antisense DNA Vaccines
- Biologic Based Anti-inflammatory Therapeutics
- Biologic Based Cardiac Pacemakers
- Biologic Based Cancer Therapeutics
- Biological Signaling Molecules
- DNA Regulatory Elements
- Gated Liposomes for Drug Delivery
- Modulation of Apoptosis with Biologics
- Plasmid Expression Vectors
- Protein Pharmaceuticals, Compositions and Formulations
- Transgenic Plants
- Vaccines
- Cancer Imaging Assays
- Carbon Nanotube Based Assays
- Co-Immunoprecipitation Assays
- Gene Expression Assays
- Micro-arrays
- Virus-Based Diagnostic Assays
- Yeast Two-Hybrid and Three- Hybrid Assays
- Animal Models of Disease
- Cell and Tissue Culture Methods
- Microfluidics
- Plant Tissue Culture
- Protein and Nucleic Acid Separation/ Purification
- Recombinant Protein Expression
- Fluid Chemistry
- Herbicidal Compositions and Formulations
- Metal alloys
- Organic Synthesis
- Organometallocene Chemistry
- Pesticidal Compositions and Formulations
- Polymer Chemistry and Methods
- Resins/Dispersions
- Silicone Chemistry
- Small Molecule Pharmaceuticals, Compositions and Formulations
- Thermoplastics
- Cosmetics
- Fermentation and Extraction
- Food Spoilage Detection Assays
- Food Ingredients
- Functional Food Platforms
- Hair Care Associated Products
- Nutraceuticals
- Therapeutic Plant Extracts

Medical Devices, Kits and IT Systems

- Vascular Stents
- Coated Vascular Stents
- Remote Endarterectomy Devices
- Stent Placement and Manipulation Devices
- Catheters
- Suture Anchor Assemblies
- Cryopreservation
- Nucleic Acid Purification
- Insertion instrument for vena cava filter
- Valve cutter for arterial bypass surgery
- Biofeedback activated orthosis for foot-drop rehabilitation
- Bidirectional suture anchor
- Tibial osteotomy system

Green Technologies

- Greenhouse Gas Emission Reduction Methods
- Carbon Trading Methods
- Algae, Microorganisms, and Small Aquatic Plant Systems for Production of Ethanol, Biodiesel, or Isoprene and other Alternative Fuels
- Chemical Conversion Systems for Production of Biodiesel Natural Insecticides and Herbicides

Publications

C.G. Moore, "Generic Biologic Drugs: What's in a Name?" *5 SciTech Lawyer 16* (Fall 2008)

C.G. Moore, "Federal Circuit: No. § 271(e)(1) Safe Harbor for Patented Inventions Not Regulated By FDA," *6 Health Lawyers Weekly 3* (August 22, 2008)

C.G. Moore, "Killing the Bayh-Dole Act's Golden Goose," *8 Tul. J. Tech. & Intell. Prop.* 151 (2006)

W.E. Ramage, "Business Methods Patents Survive... For Now," *IP Value 2011* (2011)

W.E. Ramage, "Gene Patents Under Attack," *Intellectual Asset Management* 63 (January 2010)

W. E. Ramage, "The Truth About Business Method Patents," *Intellectual Asset Management 59* (March/April 2009)

W. E. Ramage, "The Doctrine of Patent Exhaustion Gets Fresh Legs," *Patents in the USA 2008: A Guide for Japanese Executives* 16 (2008)

Bryan W. Jones, "*Smithkline v. Apotex*: Broadening The Scope Of Inherent Anticipation And Its Impact OnThe Patentability Of Chemical Structures," 5 *The John Marshall Review of Intellectual Property Law* 456 (2006)

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Life Sciences
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Intellectual Property

The Intellectual Property Group undertakes responsibility for the protection of inventions and other forms of intellectual property for clients ranging from start-ups to Fortune 500 companies. We obtain, defend and enforce patents, trademarks and copyrights in the United States and throughout the world. The Firm has developed relationships with intellectual property lawyers in many major foreign countries, and has facilitated applications, patents and registrations of trademarks in over 80 foreign jurisdictions.

Our attorneys have established a reputation for practical, common-sense business approaches to client concerns, as well as sophistication in dealing with a range of intellectual property issues for firms of all sizes. We have broad experience in patent representation, trademark disputes and branding concerns for our clients whether an emerging company or a Fortune 500. We help our clients manage their intellectual property assets as an integral part of a comprehensive business and competition strategy. Our attorneys are experienced in formulating overall intellectual property strategy, including substantive analysis and recommendations for branding protection of intellectual property interests. Our work includes branding audits for clients as well as brand protection work for international companies, including name dispute proceedings. We are able to offer strategy for resolving difficult freedom-to-operate obstacles, negotiating licensing agreements, and effectively utilizing existing intellectual property portfolios to strengthen clients' competitive positions. Our attorneys also have handled several hundred complex intellectual property litigation matters in numerous jurisdictions in the United States and overseas, as well as before the U.S. International Trade Commission.

The Group's attorneys are experienced in mechanical, electrical, chemical and biochemical technologies. We have secured patents in a broad array of technologies, products and services, including industrial processes and equipment; chemical compositions and processes; biomedical and chemical technologies, including peptide transporters, DNA sequences, pharmaceutical compositions and methods, stem cells, medical therapies for treatments of diseases, medical research tools and devices; electronic circuits and devices; ceiling fans, electronic programmable thermostats, lighting fixtures and optical devices; packaging and related components; rehabilitation and mobility apparatus; control systems for processes and equipment; telecommunications systems and products; electric transmission and distribution apparatuses; computer hardware and software; ecommerce applications and business methods; fishing products; beverages; textiles; financial and banking services; and various consumer products.

Biotechnology, Pharmaceuticals, and Medical Devices

The Intellectual Property Group has a core group devoted solely to this industry, with experience representing clients in matters related to medical systems, medical devices, chemical, biotechnological, and pharmaceutical patents. This includes fermentation and extraction of proteins, food additives and processes, small molecule pharmaceuticals, metallurgy, packaging materials, electronic materials and associated methods of manufacture and use, electrolysis, as well as polymeric processes and

applications. In the biotechnology field, in particular, this includes immunology, gene therapy, genomics, bioinformatics, plant biotechnology, fermentation, cancer therapy, small molecule pharmaceuticals, and biotechnology research tools.

Intellectual Property Services for the Energy Industry

Our attorneys have hands-on experience in the energy industry and have worked with some of the world's largest oil companies and service companies in patent matters which include geomechanical modeling, drill bit design, well injectivity analysis, "smart well implementation," maritime vessel designs, downhole production tools and methods, offshore drilling tools - just to name a few. Baker Donelson attorneys understand the issues from the client's perspective, having worked in the industry as engineers and consultants.

Representative Matters

- Secured portfolio of U.S. and foreign patents for startup drug-testing company that is now the exclusive testing facility for three state governments.
- Obtained patent for biosensors comprising a covalently attached monomolecular biological conjugate layer and a transducing device.
- Obtained patent for process for decellularizing soft-tissue engineered medical implants, and decellularized soft-tissue medical implants produced.
- Obtained patent for transplantable recellularized and reendothelialized vascular tissue graft.
- Obtained patent for pharmaceutical composition for treating angiocardiopathy and the method of producing thereof.
- Obtained patent for intraocular multifocal lens.
- Obtained patent for use of high frequency ultrasound imaging to detect and monitor the process of apoptosis in living tissues, ex-vivo tissues and cell-culture.
- Prosecuted patent application directed to optical sensor based on surface electromagnetic wave resonance in photonic band gap materials.
- Prosecuted patent applications directed to surgical instruments and method for corneal reformation.
- Prosecuted patent application directed to RFID-based system and method for tracking patient flow.
- Prosecuted patent application directed to system and method for human gait analysis.
- Prosecuted patent application for provisional percutaneous pedicle markers and methods of use thereof in spinal implants.
- Successfully invalidated patent by proving the claimed tool did not work as represented to the patent office or in the patent itself and obtained costs for defendant accused of infringement.
- Obtained product exclusion order from the United States International Trade Commission (ITC) against foreign and domestic companies importing into the United States products that infringed two U.S. patents of the client.
- Obtained consent judgment and withdrawal of trademark application by defendant in trademark and trade dress infringement action relating to 4 x 4 truck tires.
- Obtained trademark registrations for client's scent-emitting products and obtained patent coverage directed to company's primary product.
- Prepared and prosecuted patent applications directed to video imaging devices used in police vehicles.
- Successfully argued and won reversal on appeal

of copyright infringement claim brought against client publishing a directory of factual information about cable systems throughout the country.

- Secured portfolio of U.S. and foreign patents for a start-up manufacturer of flexible containers that has secured production contracts with a major international foods company.
- Secured portfolio of U.S. patents for start-up manufacturer of asbestos abatement products that now has annual sales in excess of $25 million.
- Secured important U.S. patent directed to packing for high temperature, high pressure valves.
- Prosecuted U.S. patents for corrugated paperboard containers providing increased shipping and handling protection for products, including containers for outboard motors.
- Successfully enjoined competitor from copying designs of commercial refrigeration parts embodying trade dress of client.
- Successfully enjoined competitor from copying consumer packaging designs embodying trade dress of client.
- Defended and prosecuted trademark registrations and oppositions at the Trademark Trial and Appeal Board of the U.S. Patent and Trademark Office, including oppositions concerning trade dress for thermoformed consumer food packaging products, concerning trademark for tobacco products, and concerning trademark for beverage for dogs.
- Successfully litigated domain name registrations that infringed clients' marks.
- Enjoined infringing use of client's trademark and trade dress for firearms.
- Prepared and prosecuted patent applications for apparatus and method for earth-retaining walls made of cementitious blocks and soil reinforcement sheets.
- Obtained patent coverage directed to small aperture sheets for stabilization of earthen slopes.
- Successfully defended foundation against copyright infringement, RICO, fraud and implied trust claims concerning rights of alleged visionary to publications and assets of nonprofit organization.
- Obtained monetary relief from defendant in patent infringement action concerning improved template technology for "instant-photo"-type cameras.
- Handled patent infringement action concerning apparatus for dispensing checks, money orders and other negotiable instruments.

Representative Clients

- American Contract Bridge Company
- Arcade Marketing, Inc.
- Arre Industries, Inc.
- Bayer AG
- Casablanca Fan Company
- Chattanooga Orthopaedic Group
- First Tennessee Bank
- Frontier National Corporation
- Gordon Biersch Brewery
- Hunter Fan Company
- Life Care Centers of America
- Mid-South Milling Company
- Morgan Keegan & Company
- North American Container Corporation
- Regal King
- Rexel, Inc.
- Stewart Water Solutions
- Thiele Kaolin Company

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Legal Project Management
BakerManage

Demonstration

March 5, 2012

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What are Clients Looking for from their Attorneys?
Association of Corporate Counsel (ACC)

In September and August 2011, the ACC conducted its 11th Chief Legal Officer Survey which identified clear guidance on what outside counsel can do to improve the value of services to their client:

- Efficient staffing of matters
- Improved budgeting and matter management
- Early case assessment
- Regular communications
- Clear billing
- Understanding the client's business needs

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What are Clients Looking for from their Attorneys?
Association of Corporate Counsel (ACC)

In February of 2012, the ACC conducted a Legal Service Management Workshop and identified the following traits of the "Perfect Law Firm" :

- Ask before making a change in the matter
- Be responsive
- Plan the work and work to the plan
- Design the representation to align with our business needs
- Prepare budgets and provide estimates for briefing and research
- Provide accurate and timely billing
- Provide appropriate staffing and alternate staffing solutions
- Perform a post mortem and analyze with the team what went right and what went wrong

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Legal Project Management
What is it and how can it help?

- In today's economic climate, being a legal expert is not enough.
- Exceptional legal service includes being a good steward of our client's resources and providing predictable costs.
- For years, other industries such as manufacturing, construction and engineering have seen the efficiencies that can be realized by implementation of project management processes and developing a detailed plan for scope, tasks, schedules and budgets before beginning the project.
- Baker Donelson identified that these same benefits can be derived in the delivery of legal services.

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Legal Project Management
What is it and how can it help?

- Legal Project Management. The application of the principles of project management to legal cases/matters to efficiently manage legal matters with the following goals:
  - Completed within time constraints,
  - Completed within budget,
  - Utilizing assigned resources effectively and efficiently,
  - Accepted by the client.

- Skills of a Legal Project Manager: Must be a good communicator, organized, have an understanding of budget constraints, conflict management, leadership and team-building skills. Legal project management complements what successful attorneys already know and do.

- Justification: Legal project management is not just about AFA's. "We will be good stewards of our client's resources regardless of the fee arrangement."

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Baker Donelson's LPM Solution:
BakerManage

- BakerManage draws upon traditional project management concepts and promotes implementation by providing attorneys with the tools needed to incorporate these principals into their practice.

- The objectives of BakerManage:

  - Provide consistent legal services at a predictable cost
  - Develop processes to manage legal matters efficiently
  - Provide tools for enhanced communication
  - Provide tools for client communication and oversight
  - Promote post matter review by both the team and client

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BakerManage:
How can it help reduce attorneys fees?

Budget

- Outside counsel makes more money if more hours are billed (*budget controls*)
- No budget is prepared or there is a failure to adhere to the budget (*budget controls)*
- No historical data on cost (*time entry using coding*)
- Not leveraging prior work product (*process maps, checklists, knowledge management*)
- Unrealistic expectations of time and cost (*collaboration on budget development*)
- Relationship partner does not see the bill for 30+ days (*real time budget to actual*)

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BakerManage:
How can it help reduce attorneys fees?

Resource Allocation

- Outside counsel drives the resource allocation (*client access to budgets and resources)*
- Overstaffing a matter or wrong resources (*budgets and resource allocation guidance)*
- Lack of accountability - client will pay anyway (*should we accept this, or help the client prepare a project plan?)*
- Productivity in the firm (*shifting work to resources who are not busy)*

CERTIFICATE OF ATTENDANCE

BAKER, DONELSON, BEARMAN, CALDWELL & BERKOWITZ, PC

INTELLECTUAL PROPERTY SYMPOSIUM

This is to certify that _____ attended the above-referenced seminar presented by the law firm of Baker, Donelson, Bearman, Caldwell & Berkowitz, PC on March 20 - 22, 2012 in New Orleans, Louisiana

_____

Brittany Meeker
Events Manager
Baker, Donelson, Bearman, Caldwell & Berkowitz, PC