Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

December 2014 USPTO Interim Guidance on Subject Matter Eligibility

What is Left for Diagnostics?

MIND + MUSCLE

January 22, 2015

SKGF.COM

Three-part webinar series on subject matter eligibility in *ex parte* examination

2014 Interim Guidance on Patent Subject Matter Eligibility

79 Fed. Reg. 74,618 (Dec. 16, 2014)
http://www.uspto.gov/patents/law/exam/interim_guidance_subject_matter_eligibility.jsp

New Nature Based Product Examples
http://www.uspto.gov/patents/law/exam/mdc_examples_nature-based_products.pdf

Webinars in series:

- **What Constitutes "Non-Naturally Occurring" Subject Matter?**
  January 14, 2015, 2:00 - 3:00 pm EST (http://www.skgf.com/news/uspto-101-guidelines-what-constitutes-non-naturally-occurring-subject-matter)

- **Effects on Software Patents**
  January 16, 2015, 2:00 - 3:00 pm EST (http://www.skgf.com/news/uspto-101-guidelines-effects-on-software-patents)

- **What is Left for Diagnostics?**
  January 22, 2015, 2:00 - 3:00 pm EST

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Why Prosecuting Diagnostics Applications are So Difficult

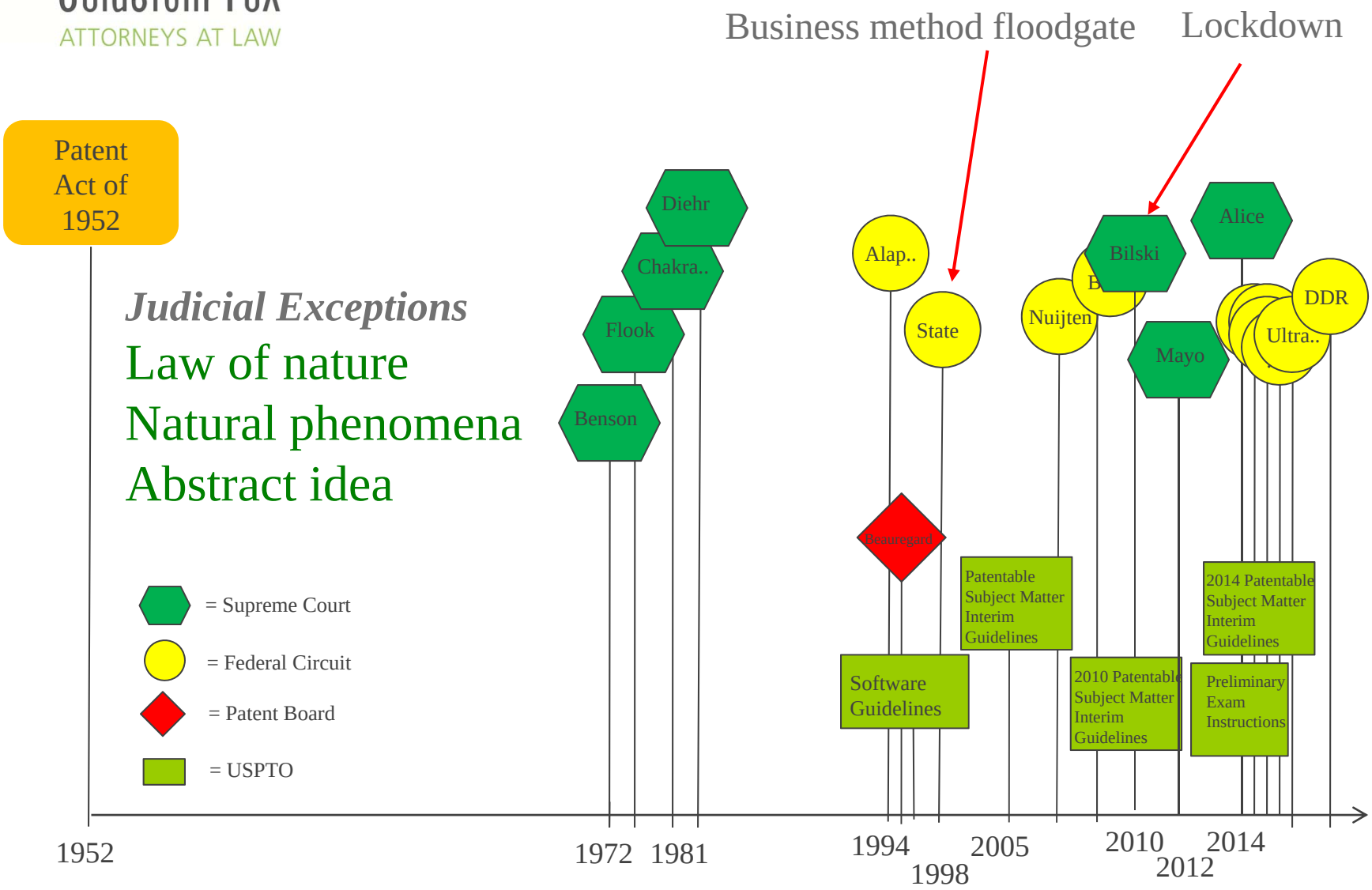
- Must deal with "naturally occurring" case law

AND

- May need to deal with "abstract idea"

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Historical Context - eligibility



Nature-based products

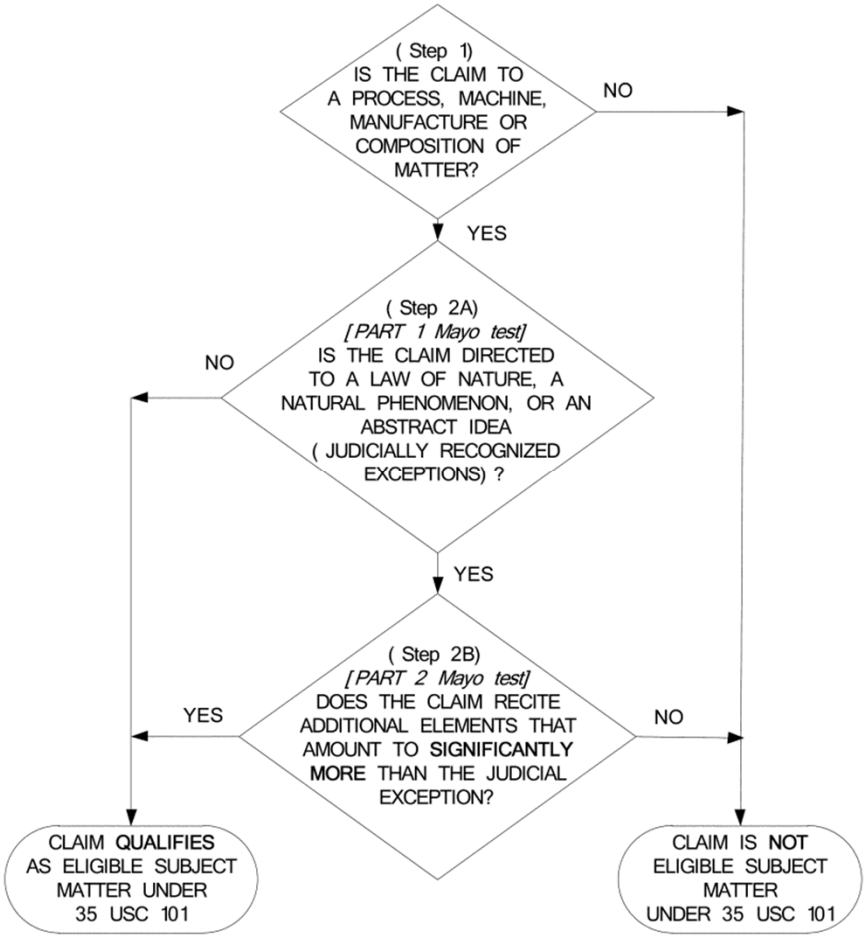
Nature-based products

- is a term used in the Guidance to refer to types of products that are examined to identify product of nature exceptions to patentability;
- include both patent eligible and ineligible products; and
- include both naturally occurring products and man-made products.

Nature-based products discussed in the Examples include:

- Gunpowder
- Beverage composition
- Naturally occurring pharmaceuticals
- Purified proteins
- Genetically modified bacterium
- Mixture of bacteria
- Nucleic acids
- Antibodies
- Cells
- Food

New Guidance maintains two-part analysis for judicial exception to patentability …

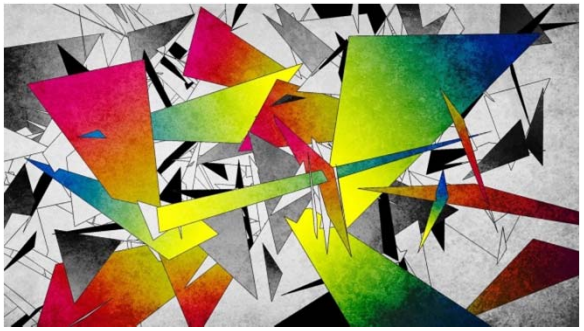


Step 2A: Does the nature-based product limitation exhibit markedly different characteristics from its naturally occurring counterpart?

Yes → claim is deemed **eligible** because it is not directed to a product of nature exception (claims reciting a law of nature or abstract idea need further analysis).

No → claim needs to be **further analyzed** in Step 2B because it is directed to a product of nature exception

Step 2A (Part 1 of *Mayo* test)



- Determine whether the claim **is directed to** a law of nature, a natural product, or an abstract idea
  - "Directed to" means "recited in the claim"
- Streamlined analysis if invention recites judicial exception, but clearly does not preempt
- Identify the judicial exception recited in the claim

Exemplary Laws of Nature and Natural Phenomena

- An isolated DNA (*Myriad)*
- A correlation that is the consequence of how a certain compound is metabolized by the body (*Mayo*)
- Electromagnetism to transmit signals (*Morse*)
- Chemical principle underlying union between fatty elements and water (*Tilghman*)

Exemplary Abstract Ideas

- Mitigating settlement risk (*Alice*)
- Hedging (*Bilski*)
- Creating a contractual relationship (*buySAFE*)
- Using advertising as an exchange or currency (*Ultramercial*)
- Processing information through a clearinghouse (*Dealertrack*)
- Comparing new and stored information and using rules to identify options (*SmartGene*)
- Using categories to organize, store, and transmit information (*Cyberfone*)
- Organizing information through mathematical correlations (*Digitech*)
- Managing a game of bingo (*Planet Bingo*)
- Arrhenius equation for calculating the cure time of rubber (*Diehr*)
- Formula for updating alarm limits (*Flook*)
- Mathematical formula for standing wave phenomena (*Mackay Radio*)
- Mathematical procedure for converting one number to another (*Benson*)

Step 2B (Part 2 of *Mayo* test)

- Determine whether any element or combo of elements in the claim is sufficient to ensure that the claim amounts to **significantly more** than the judicial exception
  - AKA "search for an 'inventive concept'"
  - Ensures that the exception is applied "in a meaningful way"

- "Every claim must be examined individually, based on the particular elements recited therein, and should not be judged to automatically stand or fall with similar claims in an application."

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

What is "significantly more"?

- Improvements to another technology or technical field
- Improvements to the functioning of the computer itself
- Applying the judicial exception with, or by use of, a particular machine
- Effecting a transformation or reduction of a particular article to a different state or thing
- Adding a specific unconventional limitation or step

What is not "significantly more"?

- Adding the words "apply it"
- Mere instructions to implement the idea on a computer
- Appending well-understood, routine, and conventional activities previously known to the industry, specified at a high level of generality
- Adding insignificant extrasolution activity (e.g., data gathering)
- Linking use of the judicial exception to a particular technological environment or field of use

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Examiner must:

- Identify the judicial exception by referring to where it is recited in the claim
- Explain why it is considered a judicial exception
- Identify other elements in the claim and explain why they do not add significantly more

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

PTO INTERIM GUIDANCE FRIENDLIER TO DIAGNOSTIC INVENTIONS

Nucleic Acids

Exemplary Claims:

1. *Isolated nucleic acid comprising SEQ ID NO: 1.*
2. *Isolated nucleic acid comprising a sequence that has at least 90% identity to SEQ ID NO: 1 and contains at least one substitution modification relative to SEQ ID NO: 1.*
3. *The isolated nucleic acid of claim 1, further comprising a fluorescent label attached to the nucleic acid.*
4. *A vector comprising the nucleic acid of claim 1 and a heterologous nucleic acid sequence*

Analysis:

- Under *Myriad*, this isolated but otherwise unchanged nucleic acid of **Claim 1** is **INELIGIBLE**;
- Structural differences between the nucleic acids of **Claim 2** and their natural counterparts are markedly different → **ELIGIBLE. However, later discovered natural variant, for example the homologue of a related species may render Claim 2 ineligible. Claim may lack written description**.
- Claim 3 is **ELIGIBLE**. Claimed molecule has different structural and functional characteristics than naturally occurring nucleic acid.
- Claim 4 is **ELIGIBLE** because claimed vectors comprise a non-natural combination of sequences from different organisms.

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

BUT WAIT . . .
THERE'S MORE

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Myriad

Day after Interim Guidelines published, Federal Circuit issued its decision in *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation* (Fed. Cir. December 17, 2014)

Representative composition claim at issue:

A pair of single-stranded DNA primers for determination of a nucleotide sequence of a BRCA1 gene by a polymerase chain reaction, the sequence of said primers being derived from human chromosome 17q, wherein the use of said primers in a polymerase chain reaction results in the synthesis of DNA having all or part of the sequence of the BRCA1 gene.

Federal Circuit:

- Primers are not distinguishable from isolated DNA found patent-ineligible by Supreme Court
- Primers necessarily contain identical sequence of BRCA sequence directly opposite to strand to which designed to bind

Myriad con't

Representative method claims at issue:

7. A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises comparing germline sequence of a BRCA1 gene or BRCA1 RNA from a tissue sample from said subject or a sequence of BRCA1 cDNA made from mRNA from said sample with germline sequences of wild-type BRCA1 cDNA, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject[,] *wherein a germline nucleic acid sequence is compared by hybridizing a BRCA1 gene probe which specifically hybridizes to a BRCA1 allele to genomic DNA isolated from said sample and detecting the presence of a hybridization product wherein a presence of said product indicates the presence of said allele in the subject*.

8. A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises comparing germline sequence of a BRCA1 gene or BRCA1 RNA from a tissue sample from said subject or a sequence of BRCA1 cDNA made from mRNA from said sample with germline sequences of wild-type BRCA1 cDNA, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject[,] *wherein a germline nucleic acid sequence is compared by amplifying all or part of a BRCA1 gene from said sample using a set of primers to produce amplified nucleic acids and sequencing the amplified nucleic acids*.

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Myriad con't

- Federal Circuit:
  - Laws of nature are not the only implicit exception to patentable subject matter identified by 35 U.S.C. § 101 – natural phenomena and abstract ideas are also not patentable
  - Beginning of claims (methods, directed to identifying alterations of the gene) require merely comparing patient's gene with wild-type and identifying any differences that arise
  - Number of covered comparisons is unlimited
    - Not restricted by purpose of comparison or alteration being detected
    - Covers detection of yet-undiscovered alterations, as well as comparisons for purposes other than cancer detection
    - Even with respect to cancer, comparisons are not limited to breast or ovarian cancer

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Myriad con't

- Federal Circuit con't:
  - Having determined comparison steps are abstract ideas, must ask whether particular mechanism for comparisons renders claims patent-eligible
  - Must ask whether remaining elements, either in isolation or combination with other non-patent-ineligible elements, are sufficient to "'transform the nature of the claim' into a patent eligible application"
  - Claim 7 requires (1) hybridizing a BRCA gene probe and (2) detecting the presence of a hybridization product
  - Claim 8 requires (1) amplifying the BRCA1 gene and (2) sequencing the amplified nucleic acids
  - Hybridization and amplification steps do nothing more than spell out what practitioners already knew – how to compare gene sequences using routine, ordinary techniques

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

So what do we do with diagnostic inventions?

ISSUED PATENTS

NEW INNOVATION

PENDING APPLICATIONS

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Things to remember

- The PTO Guidelines do not have the force of law
- Courts are not bound by the PTO Guidelines
- The law is changing – however, unlikely PTO will issue new Guidelines in light of latest *Myriad* decision

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Invest Strategically

- Is the invention important to my company?
- Is the invention technological or entrepreneurial?
- Is anything created by the invention?
- Does the invention involve a physical thing?
- Is the invention fundamental or incremental?
- Is the invention revolutionary?
- Will the invention be implemented?
- Do we intend to enforce/license the patent?
- Will I be able to maintain invention as a trade secret?

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Evaluate Current Portfolio

- Evaluate for 101 vulnerability
  - Group into subject matter categories, focus on those most in danger
  - Analyze prior to broadening reissue due dates
  - Analyze as maintenance fees become due
  - Analyze in advance of enforcement/licensing
- Take action where needed/warranted
  - Evaluate value
  - Pursue remedial measures

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

Practice Tips

- Focus on “markedly different” test to prove claimed embodiment is not “law of nature”; difficult to prove “significantly more”
  - Use Guidance and Examples to craft strategy for establishing eligibility of nature based compositions
  - For example, consider adding element that probe contains marker (radiolabel, fluorescent marker, etc.) so it is no longer “law of nature” under Step 2A of Guidelines.
- For new application, describe properties and include data that show markedly different characteristics.
- For existing applications, draft claims to compositions that are markedly different from naturally occurring products.
  - Consider preparing declaration to submit data establishing markedly different characteristics.

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

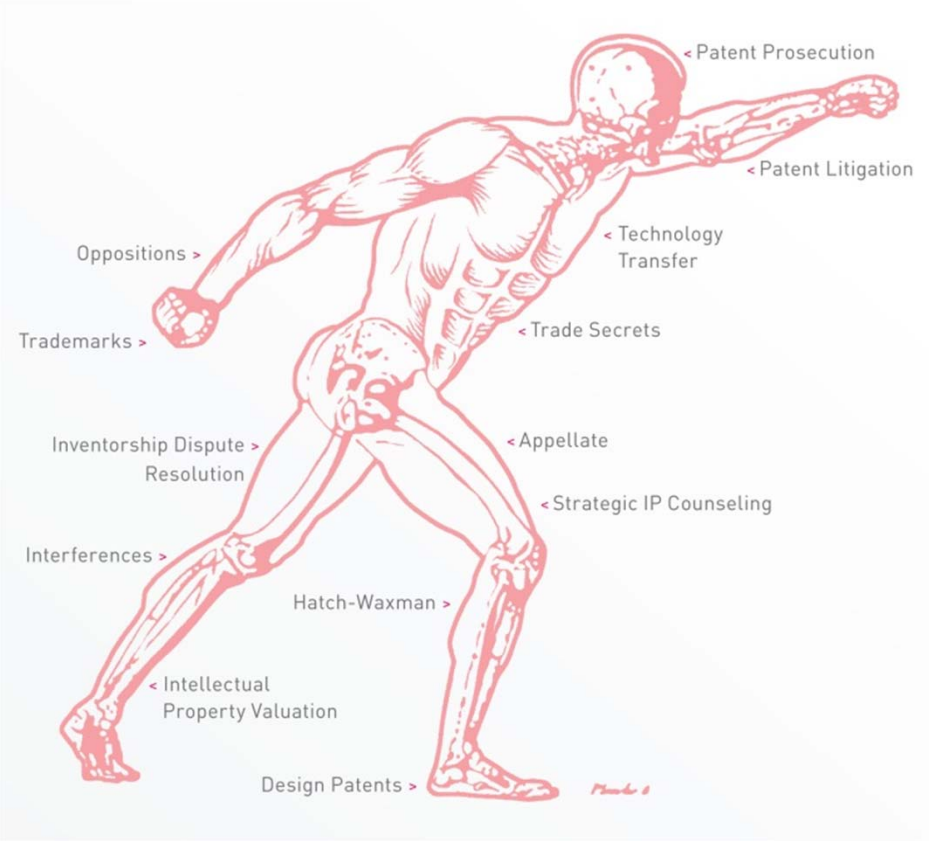
Practice Tips con't

- Rely on "significantly more" prong only if there are no markedly different characteristics.
- Establish multiple markedly different characteristics to support eligibility to ward against a later-discovered naturally existing composition rendering the claim ineligible.
- Be prepared for surprises; this is a rapidly evolving area of patent law.

Practice Tips for Diagnostic Tools

- For diagnostic tools, may need to address scope and applicability of an identified abstract idea
  - Consider expert declarations rebutting Examiner positions
    - Showing that the idea is not fundamental
    - Showing that an explicit technological implementation is required
    - Showing inventiveness/importance of the “something more”
- Consider whether an argument exists under the machine-or-transformation test
- Compare and contrast to recent software examples (e.g., *DDR Holdings* and *Ultramercial*)
- Consider whether claim amendments could help
- Strategically delay or abandon when necessary

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW



For more information:

Marsha Rose Gillentine
mgillentine@skgf.com

Michelle Holoubek
holoubek@skgf.com