USPTO Public Forum
Guidance on Subject Matter Eligibility
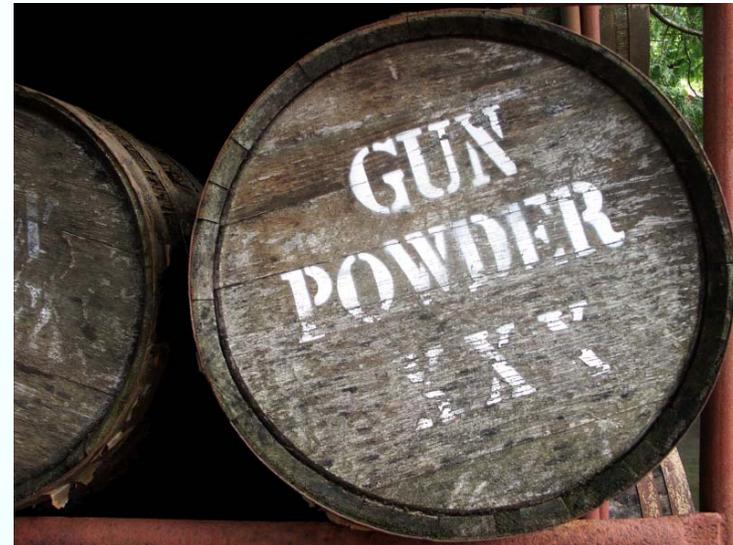
Anthony D. Sabatelli, PhD, JD

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DILWORTH IP
INTELLECTUAL PROPERTY LAW

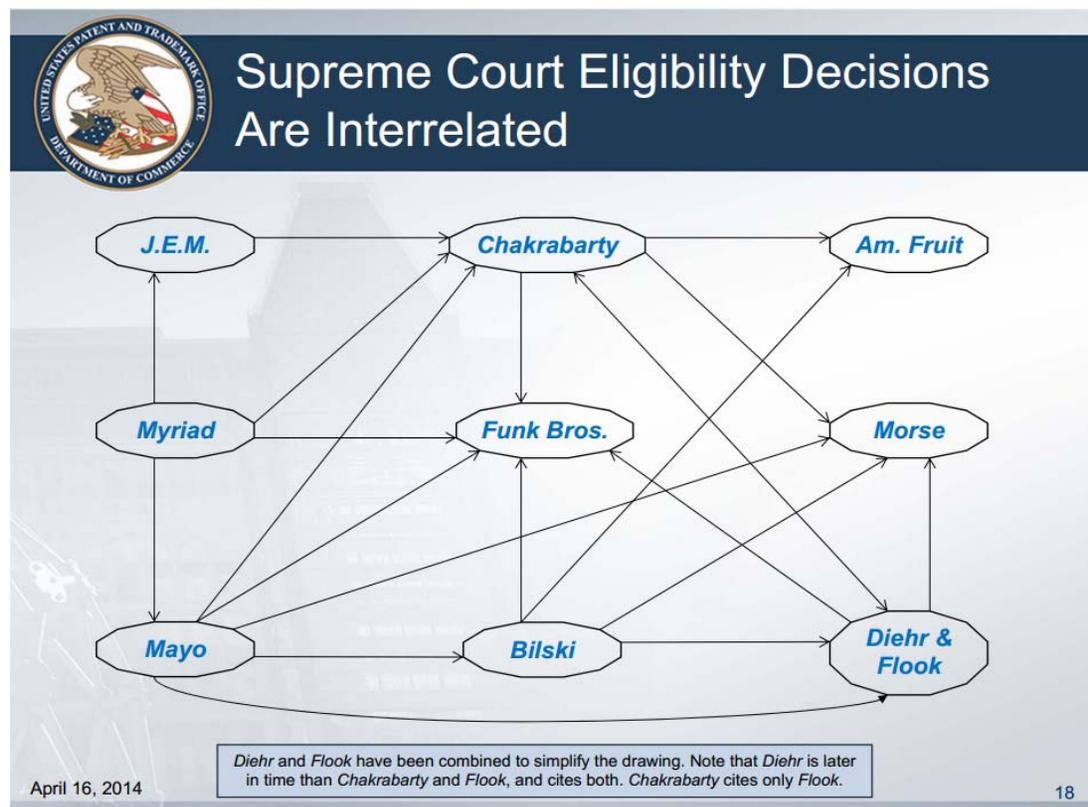# Patent Eligible?

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Overview

- Necessity for the Guidance
  - a step in the right direction
- Factor Analysis – "Significantly Different"
  - too many factors; too complex?
  - do we need a brighter, simpler line?
- Caveat – will the Factor Analysis now bring in § 102 and § 103 through the back door?
- Proposal for further Guidance Examples

The Guidance

- We applaud the USPTO for taking the leadership to issue the Guidance
  - something had to be done
  - an initial step in the right direction
- The USPTO analyzed the complex interplay of at least ten major Supreme Court decisions

Guidance Integrates Considerable Amount of Case Law

Source USPTO: Biotechnology/Chemical/Pharmaceutical Customer Partnership
April 16, 2014 Evaluating Subject Matter Eligibility Under 35 USC § 101

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Factor Analysis

- Too many factors?
- Not easy to apply
- More factors likely to be generated
  - by the USPTO
  - by case law

Factor Analysis

- Guidance asks whether the "claim as a whole" recites something "significantly different" from the judicial exceptions?

- Begs the question of whether . . .

to simplify the factors?

 - combine together the "for" factors b) – f) and combine together the "against" factors h) – l)?

§ 102 and § 103 through the back door?

- Concern that the Factor Analysis can be misapplied
- Purpose is to make the § 101 determination
  - patent eligibility, not patentability
- But . . .
  - the factors almost seem to be asking § 102 and § 103 type inquiries

Safeguards to prevent such misapplication?

Proposed Examples

***Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005)**

- high profile Supreme Court decision expanding safe harbor drug development activities under 35 USC § 271(e)(1)

- 5 patents* involved (§ 101 was not at issue)

- claims could provide useful examples

*US Patent Nos. 5,695,997, 4,988,621, 4,879,237, 4,789,734, and 4,792,525 (expired).

Merck v. Integra Examples

The following are just 3 claim examples

– suggest the USPTO carefully reviews *all* the claims for best examples

US Patent No. 4,792,525 – Purified, Non-Naturally Occurring Peptide

Claim 8. A substantially pure peptide including as the cell-attachment-promoting constituent the amino acid sequence Arg-Gly-Asp-R wherein R is Ser, Cys, Thr or other amino acid, said peptide having cell-attachment-promoting activity, and said peptide not being a naturally occurring peptide.

Merck v. Integra Examples

"Pure Research Tool" Claims

(according to J. Rader dissent in Fed. Cir. decision on remand)

US Patent No. 4,879,237 – Method for Detaching Cells from a Substrate

Claim 4. A method for detaching animal cells from a substrate to which they are bound in an Arg-Gly-Asp mediated manner, comprising contacting said bound cells with a solution containing a non-naturally occurring peptide consisting essentially of the amino acid sequence Arg-Gly-Asp-Y, wherein Y is any amino acid such that the peptide has cell-detachment activity.

US Patent No. 4,789,734 – Purified Cell Surface Receptor

Claim 1. A substantially purified cell surface receptor derived from mesenchymal tissue and capable of binding to a peptide containing the amino acid sequence Arg-Gly-Asp, comprising a glycoprotein composed of at least two polypeptides of about 115 and 125 kD, respectively, as determined by SDS-PAGE under reducing conditions which selectively binds to vitronectin, but not to fibronectin.

Summary

- The Guidance is necessary
  - a step in the right direction
- Factor Analysis should be simplified
- Caution against misplaced use of Factor Analysis
  - patent eligibility, not patentability
- Proposal for further Guidance Examples

Thank you for your time.

Anthony D. Sabatelli, PhD, JD

Partner, Dilworth IP

203-220-8496

asabatelli@dilworthip.com

www.dilworthip.com