USPTO Public Forum
Guidance on Subject Matter Eligibility

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Patent Eligible?
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
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.

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