

# 2012 SUPREME COURT AND FEDERAL CIRCUIT UPDATE

Significant Recent Patent Opinions

more *Insight.*

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## Overview

- A. This year's most significant opinions run the gamut, but many focus on statutory subject matter under Section 101
- B. The Federal Circuit is at 11 judges with the recent addition of Evan Wallach
- C. President Obama's latest nominee is Richard Taranto
  - ▶ Private practice litigator with significant patent and Supreme Court experience
- D. Feel free to ask your questions as we go. Many cases to discuss, and not a lot of time to do it.

# Patentable Subject Matter - §101

- *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, \_\_\_\_ U.S. \_\_\_\_ (2012)
- Is the Federal Circuit's MoT test dead?
- Claims: medical diagnosis

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  $8 \times 10^8$  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  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

## Patentable Subject Matter - §101

- Federal Circuit – held: Claims are patentable because chemical transformation takes place – drugs metabolize
- Supreme Court – Parsed steps
  - administering – simply identifies interested group
  - determining – conventional activity
  - Wherein – recited “natural laws”
- Claims did not do “significantly more” than describe natural phenomena and recite conventional correlations
- Compared claims to those in *Diehr* and *Flook*
- Policy considerations – patents should not inhibit future research/discovery by improperly tying up laws of nature
- Rejected placing initial focus on §§102, 103, and 112

## Patentable Subject Matter - §101

### Take Aways:

- Medical diagnostic claims now suspect, even ones that involve chemical or physical transformations
- More narrowly written claims may be unenforceable as practical matter – Federal Circuit’s divided infringement case law
- Scope of *Prometheus* holding/dicta – applicable to other technologies? Business methods, computer-implemented claims
- What about (arguably) products of nature? *Myriad*

## Patentable Subject Matter - §101

- ***Association for Molecular Pathology v. USPTO***, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted, decision vacated, and case remanded*
  - Seven patents – composition of matter claims – DNA sequences and cDNA; diagnostic method claims; cancer screening method claim
  - District Court – all claims fail to pass muster under §101
  - Fed. Circuit – rev'd-in-part
    - Standing challenge
    - Isolated DNA – Lourie: yes; Moore: maybe; Bryson:no
    - cDNA – all yes
    - Diagnostic claims – all no
    - Cancer screening claims – all yes
  - What effect will *Prometheus* have on remand?

## Patentable Subject Matter - §101

Other §101 Cases:

- ***Classen Immunotherapies, Inc. v. Biogen Idec***, 659 F.3d 1057 (Fed. Cir. 2011)
  - Claims to correlation between childhood immunizations and medical disorders later in life
  - Two sets of claims
    - Last step – “immunizing;” majority (Newman, Rader) – yes; Moore - no
    - Last step “comparing;” – all no
  - Approach – use §101 as “coarse filter;” focus on §§102, 103, 112
  - Rader additional views – warned of too narrowly construing §101
  - Petition for cert. pending – will Sup. Ct. remand?

## Patentable Subject Matter - §101

***Cybersource Corp. v. Retail Decisions Inc.***, 654 F.3d 1366 (Fed. Cir. 2011).

- Method claims reciting steps to detect credit card fraud not patent eligible under §101 – could be carried out manually
- Computer readable medium – Beauregard claim – also not patent eligible – nothing more than instructions to carry out unpatentable method – refused to exalt form over substance
- *Alappat* distinguished – simply reciting use of computer to implement steps that could be carried out in mind, not patent eligible



## Patentable Subject Matter - §101

### ***Ultramercial LLC v. Hulu LLC***, 657 F.3d 1323 (Fed. Cir. 2011)

- Claims to advertising on the Internet – patent eligible as concrete applications of abstract idea that advertising can be monetized
- Users can view copyrighted material for free – but must view commercials
- Take Aways:
  - MoT test has virtually no applicability to Internet-related patents
  - *Cybersource* distinguished as being directed to purely mental steps
- Petition for cert. has been filed

## Patentable Subject Matter - §101

***DealerTrack Inc. v. Huber***, 101 USPQ2d 1325 (Fed. Cir. 2012)

- Claims directed to computer-implemented method of managing credit card applications
  - Receive data
  - Selectively forward to remote funding resource terminals
  - Forwarding funding decision data to remote application entry device
- Claims not patent eligible – directed to abstract idea; in simplest form, directed to concept of processing information through a clearinghouse
- Link to computer – not enough - "Simply adding a computer aided limitation to a claim covering an abstract concept, without more, is insufficient to render the claim patent eligible."
- J. Plager – look to §§103, 122 first before wading into “jurisprudential morass of §101”

## Patentable Subject Matter - §101

***Fort Properties, Inc. v. American Master Lease LLC***, 671 F.3d 1317 (Fed. Cir. 2012)

- 41 method claims to an investment tool enabling property owners to buy and sell properties without incurring tax liability
- Held: all claims not patent eligible; claims similar to those held unpatentable in *Bilski*
- Discussion of court's recent decisions on how claim limitations involving computers should be treated
  - Simply reciting computer implementation not enough
  - Use of machine must "impose meaningful limits on claim scope"
  - Need more than insignificant post-solution activity

## Standard of Proof – Active Inducement

***Global-Tech Appliances, Inc., et al. v. SEB S.A.***, 563 U.S. \_\_\_\_\_  
(2011)

- Egregious facts – copying, intentionally purchasing unit abroad (no US patent number), withholding information from attorney hired to perform freedom-to-practice search/opinion
- Fed. Circuit interpreted knowledge requirement of active inducement to include “deliberate indifference”
- Sup. Court – Fed. Circuit used wrong standard, but affirmed
  - Active inducement requires knowledge of patent, based on parallel contributory infringement statute and prior *Aro II* opinion
  - Adopted “willful blindness” standard from criminal law – where defendant subjectively believes that there is a high probability that a fact exists and takes action to avoid learning of that fact

## Right to Introduce New Evidence in §145 Actions

*Hyatt v. Kappos*, Docket No. 10-1219, \_\_\_ U.S. \_\_\_ (2012), affirming opinion below, 625 F.3d 1320 (Fed. Cir. 2010) (en banc)

- Statute provides two appeal routes: (1) direct to Fed. Cir.; and (2) to district court 1<sup>st</sup>, then to Fed. Cir.
- Long time practice – no new evidence permitted in district court action unless showing could be made that evidence could not have been presented earlier
- Hyatt wanted to introduce declaration in support of 112,1 written description
- Fed. Cir. – panel opinion, split 2-1 affirming SJ denying entry of new evidence
- But, en banc court reversed; held: (1) an applicant is entitled to introduce new evidence in a §145 action subject only to the Federal Rules of Evidence and Rules of Civil Procedure; and (2) that if new evidence is introduced, the district court must review all of the evidence de novo

## Right to Introduce New Evidence in §145 Actions

### *Hyatt v. Kappos (continued)*

- Supreme Court – 9-0 affirmed
  - Nothing in statute to limit introduction of new evidence
  - For new evidence, district court must make de novo findings; not deferential APA standard
  - Will not encourage applicants to hold back evidence in PTO
  - Sotomayor – district court's still have discretion to exclude evidence deliberately suppressed or withheld in bad faith

## HATCH WAXMAN ACT (ANDA) COUNTERCLAIMS

*Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. \_\_\_\_  
(2012)

- Novo's patent on Prandin® expired, but method of use claims for Prandin plus metformin patent still in force
- Caraco – wanted to market generic repaglinide; section viii statement that label would be for uses not covered by patent
- Novo – changed Orange Book use code from repaglinide plus metformin, to method for improving glycemic control
- FDA required Caraco to use broad label instructions – now ANDA infringed under §271(e)(2)
- Fed. Cir. – 2-1, refused to permit Caraco to counterclaim for correction of use code in Orange Book

# HATCH WAXMAN ACT (ANDA) COUNTERCLAIMS

*Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, continued

- Supreme Court 9-0 reversal
  - Court broadly read remedial provisions of admittedly “ambiguous” wording of the statute to implement intent of Congress
  - Statutory scheme contemplated that one patented use would not foreclose generic marketing for unpatented uses
  - But, regulatory scheme still requires generic to make paragraph IV certification in ANDA and wait to be sued before counterclaim can be brought
  - Sotomayor concurrence
    - Statute needs to be fixed
    - Much fault lies with FDA



## INTERVENING RIGHTS REEXAMINATION

*Marine Polymer Techs., Inc. v. HemCon, Inc.*, 102 USPQ2d 1161 (Fed. Cir. 2012) (en banc)

- Claims to naturally-occurring polymer (p-GlcNAc) used for treating wounds; some claims recited biocompatible (no negative reaction when contact human tissue); some claims – no detectable biological reactivity; other dependent claims – “some” bio-reactivity
- District court infringement suit – construed biocompatible claims to cover no reactivity; SJ of infringement and \$40 million in damages
- HemCom- requested reexam during pendency of law suit; examiner construed “biocompatible” claims to include some bio-reactivity (“broadest reasonable”); Marine cancelled dependent claims reciting some bio-reactivity and argued successfully that independent claims were now limited to no bio-reactivity

## INTERVENING RIGHTS REEXAMINATION

*Marine Polymer Techs., Inc. v. HemCon, Inc.*, continued

- Hemcon appealed judgment to Fed. Cir. arguing that because of the arguments made during reexam, the scope of the claims had changed and Hemcon was entitled to intervening rights pursuant to 35 USC §307(b) and 316(b) – 2-1 reversed judgment, wiping out the \$30 million damages
- J. Lourie dissented on panel opinion, then wrote majority opinion (6-4) for en banc court
  - Intervening rights apply only to new or amended claims
  - No claims were amended; argument insufficient
  - Doctrine of claim differentiation does not trump statute; disavowal of broader construction in spec
- Dissent: No disavowal; statute should encompass amendment without language change because scope of claims did change

## Joint Infringement – Joint Liability

- Several recent panel opinions (*BMC Resources* and *MuniAuction*) have held that where no single party performs **all** steps of a method claim, there can be no infringement and no joint liability unless one party “control[s] or direct[s]” the activities of the other party(ies)
- Now we have two cases taken en banc to settle the law in this area
- ***Akamai Techs. Inc. v. Limelight Networks Inc.***, 629 F.3d 1311 (Fed. Cir. 2010), panel opinion withdrawn and en banc rehearing granted, April 20, 2011; argued November 18, 2011
  - Method of optimizing web page display; theory of joint liability – Limelight and its customers
  - Jury found infringement; \$40 million in damages; district court granted JMOL of non-infringement based on *BMC* and *MuniAuction*; Fed. Cir. panel affirmed

## Joint Infringement – Joint Liability

***McKesson Techs. Inc. v. Epic Sys. Corp.***, 98 USPQ2d 1281 (Fed. Cir. 2011), panel opinion withdrawn and en banc rehearing granted; argued November 18, 2011

- Again, Fed. Cir. panel affirmed finding of no joint infringement; no joint liability
- J. Bryson – concurred, but commented on need for en banc review

## Inequitable Conduct

***Therasense, Inc. v. Becton Dickinson & Co.***, 649 F.3d 1276 (Fed. Cir. 2011) (*en banc*).

- By slim 6-5 majority, court has now tightened the standards for pleading and proving inequitable conduct
- Patents: glucose test kits; issue was withholding of arguably contrary position taken by patentee during European prosecution; district court found inequitable conduct under then-current standard of materiality (old Rule 56) and intent
- Fed. Cir. panel; split panel affirmed – threshold level of materiality shown , and intent proved by clear and convincing evidence
- *Therasense* was one of 11 panel decisions since 2005 where the panel split on the issue of inequitable conduct
- En banc review granted

## Inequitable Conduct

*Therasense*, continued

- New test for materiality – old and new Rule 56 standards by passed for a strict “but for” test – “but for” the accused conduct, would the PTO have issued the claims in issue had it known of the withheld material
- Specific intent still required as well; standard tightened – no more “should have known” – need clear and convincing evidence that applicant (1) knew of reference/information, (2) knew it was material; and (3) made a deliberate decision to withhold it
- Knowledge may still be proved by circumstantial evidence, but specific intent to deceive must still be the single most reasonable inference
- Dissent: would have adopted PTO’s new Rule 56 standard as more practical; fears that majority had essentially “abolished” the defense have not been borne out – dist. Ct. on remand recently again found inequitable conduct applying the stricter standards, and recent Fed. Cir. panel has also upheld findings