

UPDATES ON US PATENT LAW AND PRACTICE

FOR: PIUG (Baltimore, MD, May 3, 2010)

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OUTLINE

1. LEGISLATION

2. HIGHER COURTS

3. USPTO

4. Myriad (How a Judge thinks)

1. *LEGISLATION*

- 2007 House passage of patent bill, **moot** (different legislative session)
- 111th Congress (2009/2010)
- January 3, 2009 to January 3, 2011
- INTRODUCED/STATUS

WHAT PATENT BILLS HAVE BEEN INTRODUCED?

[http://www.govtrack.us/congress/billsearch.xpd?PostFormID==billsearch&session=111&q=patent&sponsor=&cospons
or=&chamber=&status=&sort=](http://www.govtrack.us/congress/billsearch.xpd?PostFormID=<u>=billsearch&session=111&q=patent&sponsor=&cospons</u>
<u>or=&chamber=&status=&sort=</u>)

- **SEARCH FOR: PATENT, 119 HITS**

119 – BILLS INTRODUCED

11 - REPORTED BY COMMITTEE

12 - VOTED ON IN ORIGINATING CHAMBER

1 – VOTED ON IN BOTH CHAMBERS

0 – SUBSTANTIVE PATENT LAWS ENACTED

WHAT IS THEIR STATUS?

119 – INTRODUCED BILLS

11 - REPORTED BY COMMITTEE

12 - VOTED ON IN ORIGINATING
CHAMBER

1 – VOTED ON IN BOTH CHAMBERS

0 – PASSED INTO LAW

WHAT DO THESE BILLS COVER?

MAJOR SYSTEMIC PATENT REFORM

HR 1260, S 610, S 515 – Major Patent Reform. (**S 515 referred to full Senate**)

HR 628 – Set up certain District Courts as expert courts for a patent cases (Passed the House)

BIO SPECIAL INTERESTS

HR 1706 – Tweaks Hatch-Waxman to limit collusion of an ANDA filer and an ethical patentee to extend exclusivity.

S 726, HR 1427, HR 1548 - Hatch–Waxman and **bio similars!** (Bio similars market approval, process for licensing an “abbreviated biological product application”, market exclusivity, and deals with ABPA patent infringement).

HR 3299 – Regulates re-planting based upon planting of patented seeds; taxes importers of products grown from US patented seeds; tax distributed to patent pool members!.

OTHER NARROWER SPECIAL INTERESTS

HR 4954 – Rewrite the false marking statute to limit suit to injured parties (NOTE: (b) Effective Date- The amendment made by subsection (a) shall apply to all cases, without exception, pending on or after the date of the enactment of this Act.”)

S 1368 – Access to repair parts. Precludes infringement of Design patents by using repair parts the restore original Design.

HR 2584 – Makes tax planning methods unpatentable (45 cosponsors)

(Fast forward to slide 25)

S 515 PROVISIONS

Sec. 1. Short title; table of contents.

Sec. 2. Right of the first inventor to file.

Sec. 3. Inventor's oath or declaration.

Sec. 4. Right of the inventor to obtain damages.

Sec. 5. Post-grant procedures and other quality enhancements.

Sec. 6. Definitions; Patent Trial and Appeal Board.

Sec. 7. Pre issuance submissions by third parties.

Sec. 8. Venue and jurisdiction.

Sec. 9. Patent and Trademark Office regulatory authority.

Sec. 10. Residency of Federal Circuit judges.

Sec. 11. Micro-entity defined.

Sec. 12. Funding agreements.

Sec. 13. Patent and Trademark Office travel expenses test program.

Sec. 14. Best mode requirement.

Sec. 15. Pilot program in certain district courts.

Sec. 1216. Technical amendments.

Sec. 1317. Effective date; rule of construction.

Sec. 1418. Severability.

§ 515 PRIOR ART DEFINITION

- ANYTHING PUBLICLY KNOWN OR USED, **ANYWHERE**, PRIOR TO THE EFFECTIVE FILING DATE; AND
- PATENTS FROM FILING DATE

§ 515 PUBLICLY KNOWN OR USED, ANYWHERE

THIS BROADENS PRIOR ART

- PUBLIC USE ***OUTSIDE*** THE

U.S., IS NEW

- SALE ***OUTSIDE*** THE U.S., IS

NEW

§ 515 EXCEPTION TO “PUBLICLY KNOWN” RULE

- 1 YEAR GRACE PERIOD
- INVENTOR CAN DISCLOSE,
AND THEN FILE LATER
- OTHER COUNTRIES HAVE
NOT ADOPTED A GRACE
PERIOD

S 515 PATENT DOCUMENTS PRIOR ART

- US PATENT PUBLICATIONS
AND PCT PUBS IN ENGLISH
- PRIOR ART ON EARLIEST
PRIORITY DATE
- *FORIEGN PRIORITY DATES
COUNT*

CURRENT LAW VS.

§ 515

TIME →



FR

PCT

PCT PUB.
IN ENGLISH

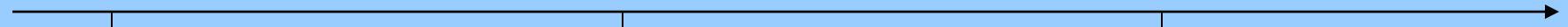


PRIOR ART
IN DATE IN
THE U.S.
UNDER S.
515 !

PRIOR ART DATE IN
THE U.S. UNDER
CURRENT LAW

CURRENT LAW VS. § 515

TIME →



FR

U.S.

U.S.
PUB.



**PRIOR ART
IN THE U.S.
UNDER S.
515 !**

PRIOR ART DATE IN
THE U.S. UNDER
CURRENT LAW

PATENT “FILING DATE” PRIOR ART EXCEPTIONS

PATENT NOT PRIOR ART IF:

- IT WAS COMMONLY ASSIGNED OR SUBJECT TO CRA AT TIME OF FILING; OR
- IT WAS DERIVED FROM TRUE INVENTOR

S 515 CONT'D –

- SEARCHER XENOPHOBIA

35 USC 131(b): “examination and search duties for the grant of a United States patent are sovereign functions which shall be performed **within the United States by United States citizens who are employees of the United States Government.**”

- Note – **NOT PRESENT IN HOUSE VERSION**

§ 515 DAMAGES LIMITATIONS

- COURT LIMITS METHODS, FACTORS, AND ADMISSIBLE EVIDENCE FOR DAMAGES
- WILLFULNESS - STANDARDS HEIGHTENED
- WILLFULNESS CANNOT EVEN BE PLEADED UNTIL AFTER A FINDING OF LIABILITY

S 515 USPTO *POST* *GRANT* PROCEEDINGS

- CANCELLATION PROCEEDING – 1 YEAR
- INTERFERENCES, NOW DERIVATION PROCEEDING – 1 YEAR
- INTER PARTES REEXAM PROCEEDING

S 515 USPTO *POST* *GRANT* PROCEEDINGS

- BPAI NOW THE PTAB (PATENT TRIALS AND APPEALS BOARD)
- PTAB, TO HANDLE ALL INTER PARTES PROCEEDINGS, CANCELLATION, DERIVATION, INTER PARTES REEXAM (INTER PARTES REEXAM VIA PTO INTERNAL RULES, IF NOT VIA STATUTE)

S 515 PRE ISSUANCE THIRD PARTY SUBMISSIONS

UNLIKE CURRENT RULES, THE S 515 WOULD RELAX THE TIMING AND CONTENT OF THIRD PARTY SUBMISSIONS, MAKING THEM A USEFUL VEHICLE TO HELP FILTER OUT UNPATENTABLE APPLICATIONS

S 515 THIRD PARTY SUBMISSION

CONTENTS:

- EVIDENCE
- EXPLANATION OF RELEVANCE TO AT LEAST ONE CLAIM
- FEE (SMALL FEE)

S 515 THIRD PARTY SUBMISSION - TIMING

- PRIOR TO THE LATER OF 6 MONTHS AFTER PUBLICATION OR FIRST OFFICE ACTION, BUT IN NO CASE AFTER NOTICE OF ALLOWANCE.
- NOTE: SEARCHERS MAY BE VERY INVOLVED IN THIS ACTIVITY

§ 515 MISC

- FAILURE TO DISCLOSE THE “BEST MODE” REMOVED FROM A POSSIBLE DEFENSE IN LITIGATION
- PTO **GRANTED** FEE SETTING AUTH.
- PTO **NOT GRANTED** SUBSTANTIVE RULE MAKING AUTHORITY

End of fast forward

HOUSE BILL DIFFERENCES FROM S 515

- GRACE PERIOD BARGAIN!
- PRES. CERTIFICATION ON GRACE PERIOD TRIGGERS
- NO SEARCH/EXAM
- XENOPHOBIA

S 515 MANAGER'S AMENDMENT *PROPOSED MARCH 2010*

- Limits false marking right to sue, to those injured, effective date would ***eliminate pending suits.***
- Supplemental examination of patents to purge and cure errors and omissions (like reexam, but ***immunizes*** prior defects)

S 515 MANAGER'S AMENDMENT *PROPOSED MARCH 2010*

“SEC. 5. POST-GRANT REVIEW PROCEEDINGS”

1. “CHAPTER 32—POST-GRANT REVIEW”
2. “CHAPTER 31—INTER PARTES REVIEW”
 - BOTH PROCEEDINGS ARE “INTER PARTES” AND BOTH OCCUR “POST GRANT”
 - THEY VARY BY ***TIMING AND SCOPE***

CHAPTER 32—POST-GRANT REVIEW

Time limit: ***Can only be filed within*** 9 months from patent grant

Scope of review: ***Expanded.*** 101, 102, 103, 112, 251 (*patentable subject matter, prior art, written description, enablement, definiteness, reissue requirements*) (Cf. Aristocrat law)

Jurisdiction: **Board of Appeals**

CHAPTER 31—INTER PARTES REVIEW

Time limits: ***Cannot be filed within*** 9 months from patent grant

Scope of review: ***Limited*** to prior art based upon patents and printed publications (Issues of claim definiteness, enablement, written description, patentable subject matter, taboo)

Jurisdiction: **Board of Appeals**

2. COURTS

- **SUPREME COURT**
- **CAFC**
- **DISTRICT COURTS ***
- **PTO**

SUPREME COURT

WHAT IS PATENTABLE SUBJECT MATTER?

- Bilski – Supreme Court *decision imminent*. (Predictions – No substantial narrowing of patentable subject matter test. At least, “machine or transformation test”)
- Possibly Prometheus, diagnosis and treatment
- Myriad, patentability of genes, per se

CAFC

- **Tafas and GSK – Dead at last!**
- New PTO Director Kappos agreed to dispose of the case.
- The specter of oppressive claim and continuations limitations, and draconian consequences, fades.

THE CAFC IS A HAPPENING COURT!

- CAFC MAKES A LOT OF LAW!**
- THE FOLLOWING GIVES YOU THE FLAVOR OF RECENT CAFC PRECEDENTIAL DECISIONS, EACH OF WHICH AFFECTS A LARGE NUMBER OF PEOPLE/COMPANIES**

CAFC FLAVOR – 1 – EN BANC

Ariad v Eli Lilly (Yes, there **IS**, a written description requirement!)(**En banc**)

Abbot v. Sandoz (Limiting scope of product by process claims to products made by the claimed process)(**En banc**)

Cardiac v. St. Jude (Supplying from the U.S. a component used outside the U.S. in a method patented in the U.S. is not infringement; 271(f)(**En banc**)

Hyatt v Kappos (scope of district court review of BPAI decisions; 145 cases, new evidence admissible?) (**order for en banc briefing**)

Therasence, Inc. v. Becton Dickinson and Co (What should the standard be for finding inequitable conduct) (**order for en banc briefing**).

CAFC FLAVOR - 1

Pressure Products v Greatbatch (Expanded panel) (112 6th means, do not include those means disclosed in prior art mentioned in the patent)

In re Chapman (Harmless error rule applies to BPAI decisions)

In re Chapman (Fair assurance test applies to whether error is harmless)

Boehringer v Barr (terminal disclaimer filed after the expiration of the earlier patent , too late)

Boehringer v Barr (divisional of a divisional protected by 121 from double patenting invalidity)

Boehringer v Barr (application claiming several restricted inventions is still a divisional)

Wyeth v Kappos (USPTO must provide patent term adjustment required by statute, ding!)

Richardson v. Stanley (Design patent scope limited to not extend to functional aspects)(request for reh'g en banc filed.)

CAFC FLAVOR - 2

Wisconsin v Xenon (statutory right of co-owners to license may be modified by contract)

Crocs v ITC (design patent infringement, side by side test for ordinary observer)

SEB v Montgomery Ward (“deliberately disregard [of] a known risk [of] a protective patent” sufficient for inducing infringement)

ResQNet.com v. Lansa (Reasonable royalty for infringement must be tied to economic harm)

Therasense, Inc. v. Beckton, Dickinson and Co. (Statement to foreign patent office contradictory to position in USPTO "highly material")

2009 CASES

Prometheus v Mayo (Mental steps may be included in claims that otherwise define patentable subject matter)(May be heard by S.Ct.)**

CAFC FLAVOR - 3

In re Lister (“Absent evidence of the date that the disclosure was publicly posted, if the publication itself does not include a publication date (or retrieval date), it cannot be relied upon as prior art under 35 U.S.C. 102(a) or (b).”)

Martek v Nutrinova (expanded panel) (Limitations on uncorroborated evidence of date of invention and public use)

Edwards v Cook (“The interchangeable use of the two terms is akin to a definition equating the two.”)

Agilent v Affymetrix (Copied claims interpreted based upon target specification for written description compliance)

In re McNeil-PPC (Date of a BPAI decision is date the PTO *actually* mailed it)

Sky Technologies LLC v. SAP AG (transfer of ownership by operation of state law does not require a writing)

CAFC FLAVOR - 4

Euclid v Vector Corrosion (Assignment language necessary to effect assignment of related applications/patents)

Amgen, Inc. v ITC (271(e)(1) safe harbor applies to process patents in ITC actions)

Imation v Philips (Present assignment of rights in future inventions can pass legal title, e.g. “agrees to grant and does hereby grant”)

Transcore v. Electronic Transaction Consultants (Unconditional covenant not to sue is equivalent to a license)

Princo v ITC (Including arguably blocking patents in an otherwise pro competitive patent pool is not unacceptable patent misuse)

In re Bose (Fraud on the PTO requires knowingly making a false, material representation, with the intent to deceive the PTO)

Exergen Corp. v. Wal-Mart Stores (PTO fraud pleadings must detail who, what, when, where, and how fraud occurred)

CAFC FLAVOR - 5

Crown Packaging Tech., Inc. v. Rexam Bev (Marking does not limit damages if only method claims of a patent are asserted)

Trex Company v. Home Depot (Issue preclusion applies as to claim construction)

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CAFC - ARIAD

- Ariad v. Eli Lilly (Fed. Cir. 3/22/2010)(en banc)
- Held – Yes, - - **there is**, - - a written description requirement separate and apart from the enablement requirement. You must describe the claimed invention.
- Gajarsa (concurring opinion)(“In my judgment, the text of § 112, ¶ 1 is a model of legislative ambiguity.”)
- Law, language, grammar, context. Comma’s make a difference!

CAFC - ARIAD

- Where is the beef?
- Universities versus manufacturers
- What is the scope of protection you can get for a fundamental discover, not yet well developed?

PTO DEVELOPMENTS

*****KAPPOS*****

PTO - KAPPOS!

- ***Buried* GSK and Tafas.**
- ***Re-motivated* the examining corps (changes to counter system)**
- **(This is the *patent* office, not the *rejection* office – change in mentality)**
- **Requesting supplemental user input on rules changes**

PTO - KAPPOS!

- Ex parte Frye, Docket No. 2009-006013 in Application 10/790,923 (BPAI 2/26/2010) (Precedential) (**expanded panel including Kappos**, per curiam)(BPAI *cannot assume that the examiner's rejections were correct!*)
- That over rules the CAPJ's guidance during the prior Director's tenure, that the appellant must show how the examiner erred, to win on appeal.

PTO - KAPPOS!

CONSEQUENCES:

- PATENT APPLICATIONS THAT SHOULD HAVE BEEN ALLOWED LONG AGO, ARE NOW BEING ALLOWED
- PATENT APPLICATIONS THAT SHOULD BE REJECTED ARE STILL BEING REJECTED
- *EXAMINERS ARE WORKING TO GET ALLOWABLE APPLICATIONS ALLOWED*

DISTRICT COURTS

MYRIAD CASE

- (Actually, Association for Molecular Biology v. USPTO)
- Motion for SJ to have claims to BRCA1/2 genes declared invalid:
Granted!
- 156 PAGE OPINION**

MYRIAD CASE ANALYSIS

- **DR. GOFFMAN WILL DISCUSS THE IMPACT OF MYRIAD**
- **TIME PERMITTING, I MAY FOLLOW UP WITH LEGAL INSIGHTS INTO MYRIAD**

SUMMARY

- MAJOR PATENT LEGISLATION CLOSER TO PASSAGE
- PATENTABLE SUBJECT MATTER IN FLUX (BILSKI, MYRIAD, ETC.)
- THERE IS A NEW DAWN OF *REASONABLE BEHAVIOR* BY THE USPTO

THE END THANK YOU!

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MYRIAD – GENE PATENTS

- Association for Molecular Biology v. USPTO
- Motion for SJ to have claims to BRCA1/2 genes declared invalid:
Granted!
- Reasoning: Genes Not Are “Patentable Subject Matter”

MYRIAD – GENE PATENTS

- JUDICIAL THINKING
- ANALYSIS OF JUDGE SWEET'S CONCLUSIONS; STATUTORY TEST
- ANALYSIS OF JUDGE SWEET'S RELIANCE ON SUPREME COURT PRECEDENT

HOW JUDGES THINK?

- 7th Circuit Court Judge Richard A. Posner, “How Judges Think”

- EQUITY
- EFFICIENCY
- SPEEDINESS
- WORK LOAD
- PUBLIC CONCERNS
- ***PRAGMATISM***

JUDICIAL THINKING

- This is a hot topic, public policy item. Its a legislative issue.
- I will have to convene a full trial, which will take a long long time, to try this case, - - if I have to try it.

JUDICIAL THINKING

- I will have to spend a long long time on that trial. My time.
- I have a big docket of other cases I have to get to.

JUDICIAL THINKING

- This is an issue which both sides will certainly take to the Supreme Court, whatever I do.
- How can I best get this case moving to ultimate resolution?

JUDICIAL THINKING

- Answer: Grant the SJ motion!
- But if I grant the SJ motion, the appellate court may remand it to me for reconsideration.

JUDICIAL THINKING

- But if I rely primarily upon Supreme Court law, the appellate court cannot easily remand it to me since they have to follow Supreme Court law, - - even if my interpretation of that law is, - - “strained.” ...

MYRIAD – LEGAL TEST

- “35 U.S.C. 101 Inventions patentable. Whoever [1] invents or discovers any [2] **new** and [3] useful [4] process, machine, manufacture, or **composition of matter**, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”
- 1952 PATENT ACT

MYRIAD – LEGAL TEST

35 USC 101

- [1] invention or discovery?
- **[2] new?**
- [3] useful?
- **[4] process, machine, manufacture, or composition of matter**

EXEMPLARY MYRIAD COMPOSITION CLAIM

‘282 PATENT CLAIM 1

“An **isolated** DNA coding for a
BRCA1 polypeptide, said polypeptide
having the amino acid sequence set
forth in **SEQ. ID. NO: 2**”

EXEMPLARY MYRIAD COMPOSITION CLAIM

SEQ. ID. NO: 2?

“(2) INFORMATION FOR SEQ ID NO:2: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 1863 amino acids (B) TYPE: amino acid (D) TOPOLOGY: **linear (ii) MOLECULE TYPE: protein (xi) SEQUENCE DESCRIPTION:**”

“ MetAspLeuSerAlaLeuArgValGluGluValGlnAsnValIleAsn

ValValGlnProAspAlaTrpThrGluAspAsnGlyPheHisAlalle

181018151820”

JUDGE – COMPOSITION CLAIM 1

- REASONING 1 – “DNA’s existing in an ‘isolated’ form *alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes.* Therefore, the patents at issue directed to ‘isolated DNA’ containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 USC 101” Pg. 4.

COMPOSITION TEST FOR PATENTABLE SUBJECT MATTER

- Judge test: Does the molecular “isolated” form alter a fundamental quality ... as it exists in the body...”?
- Statutory test: Is it “new”, and is it a “composition of matter”? (Yes, and yes.)

JUDICIAL 'EXCEPTIONS' TO PATENTABLE SUBJECT MATTER

- SEE SUPREME COURT PRECEDENT**
- (LAWS OF NATURE, NATURAL PHENOMENA, ETC)**

RELIANCE UP SUPREME COURT PRECEDENT

The American Wood-Paper Co (1847): Judge Sweet ‘purification of a natural compound, without more’ is not patentable subject matter.

In fact, S.Ct. stated that what was claimed was "a pulp suitable for the manufacture of paper, made from wood or other vegetable substances," and that that product “had been produced and used in the manufacture of paper long before 1853, the year in which the original patent of Watt & Burgess was dated.”

Lack of novelty over prior art, not a patentable subject matter issue.

RELIANCE ON SUPREME COURT PRECEDENT

American Fruit Growers (1931): *Judge Sweet* ‘changed product of nature must create a fundamentally new product’ to be patentable subject matter.

In fact, S.Ct. reversed circuit court’s holding that the patent was valid. The S.Ct. found the patent anticipated by a 1901 patent teaching the same method of coating with boracic [sic] acid to prolong fruit life. The S.Ct also found that a borax treated rind of a fruit was not a “manufacture”, contrary to the conclusion of the appeals court.

Anticipation, not ‘patentable subject matter’, and not a *composition of matter* question in any case.

RELIANCE UP SUPREME COURT PRECEDENT

Funk Brothers (1948): Judge Sweet ‘mixture of naturally occurring species not patentable subject matter’.

In fact, no mixture was claimed. “4. An inoculant for leguminous plants comprising a plurality of .. strains of ...bacteria of the genus Rhizobium.” No *mixture*, just a plurality of strains. (S.Ct. “Discovery of the fact that certain strains of each species of these bacteria *can be mixed* without harmful effect to the properties of either is ... no more than the discovery of some of the handiwork of nature and hence is not patentable.”

RELIANCE UP SUPREME COURT PRECEDENT

Diamond v. Chakrabarty (1980): Judge Sweet, 101 requires ‘markedly different characteristics’.

In fact, the S. Ct ‘markedly different characteristics “ was only in contrast to the “plurality of [naturally occurring] strains” claimed in Funk Brothers. What the S.Ct. *held* was that Chakrabarty’s “micro-organism plainly qualifies as patentable subject matter [because his] claim ... is to a *nonnaturally occurring manufacture or composition of matter -- a product of human ingenuity ‘having a distinctive name, character [and] use.’”*

MYRIAD SUMMARY

- STATUTORY CONSTRUCTION 1, J. SWEET 0
- J. SWEET'S CHARACTERIZATION OF S.C.T. PRECEDENT QUESTIONABLE
- PER Chakrabarty: The S.Ct. test is whether Myriad's "isolated DNA coding for a BRCA1 polypeptide" claim defines "a nonnaturally occurring manufacture or composition of matter -- a product of human ingenuity 'having a distinctive name, character [and] use.'"

THE END (AGAIN) THANK YOU! (AGAIN)

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