



PIPLA
Year-in-Review

May 13, 2020

Agenda

Program

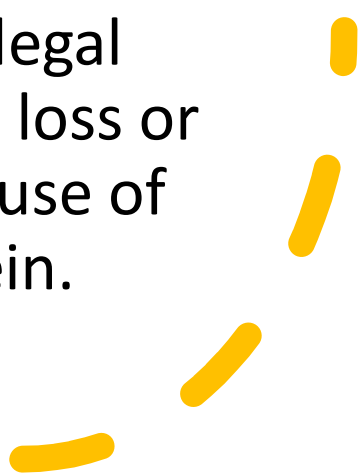
- Litigation - Melissa Gibson, Karina Moy, and Anthony Sierra (Akin Gump)
- Copyrights - Lisa Bollinger Gehman (BakerHostetler)
- Trademarks - Jacqueline M. Lesser (BakerHostetler)
- Patents – Greg Grissett (Offit Kurman)

Distinguished IP Practitioner Announcement

Elections

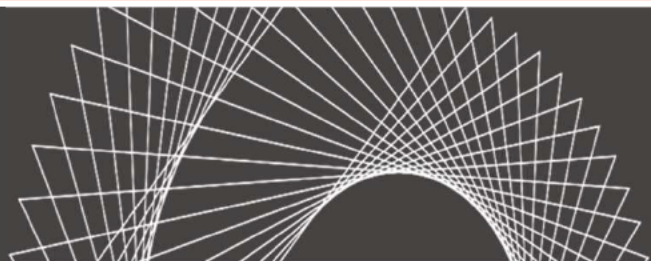
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Litigation

Federal Circuit: Year-in-Review Patent Litigation



Akin Gump
STRAUSS HAUER & FELD LLP

Melissa Gibson

Karina Moy

Anthony Sierra

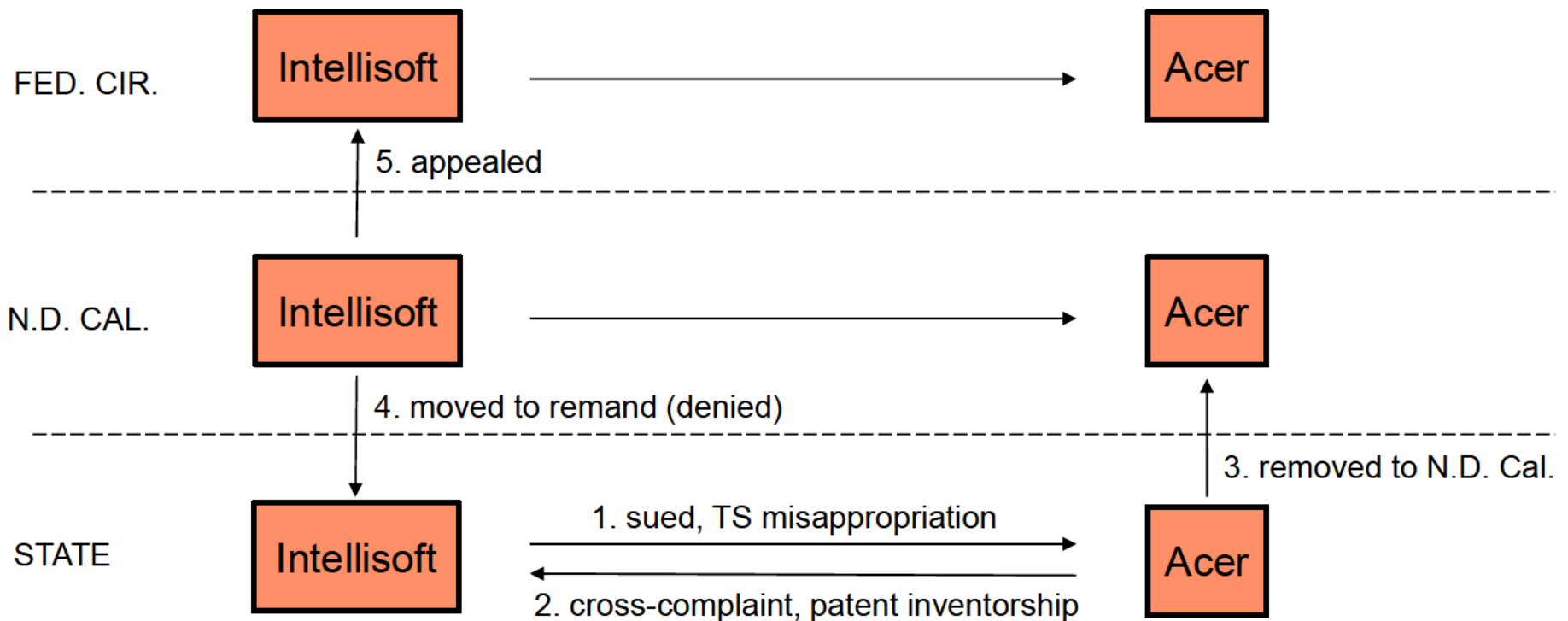
Jurisdiction



Intellisoft, Ltd. v. Acer America Corp., 955 F.3d 927 (Fed. Cir. 2020)

Factual/Procedural History

- Intellisoft shared trade secret with Acer under NDA
- Acer applied for U.S. Patent No. 5,410,713, “Power-management system for a computer,” allegedly incorporating Intellisoft’s trade secrets



Intellisoft v. Acer

Issue

Whether Federal Circuit has jurisdiction over case asserting trade secret misappropriation, based on improperly raised patent inventorship cross-complaint.

Ground for removal:

- 28 U.S.C. § 1441 – remove any action under which district court would have **original jurisdiction**
- 35 U.S.C. § 256 – correction of named inventor of patent

Gunn v. Minton test for federal question jurisdiction: *Is the federal issue:*

- 1. Necessarily raised?**
2. Actually disputed?
3. Substantial?
4. Capable of resolution, without disrupting federal/state balance?

Intellisoft v. Acer

Ground for removal:

- 28 U.S.C. § 1454 – remove any action where **patent counterclaim** is asserted

Acer never sought leave to file cross-complaint, so claim was never asserted

Held

No federal question jurisdiction over state law case with improper patent counterclaim.

Vacated and reversed, with instruction to remand to state court.



Section 101: Patent Eligible Subject Matter



Ericsson Inc. v. TCL Comm'n Tech., 955 F.3d 1317 (Fed. Cir. 2020)

Suit regarding infringement of U.S. Patent No. 7,149,510 (the '510 patent). TCL moved for summary judgment on the basis that asserted claims were ineligible under Sect. 101, but was denied.

TCL appealed on the 101 issue.

1. A system for controlling access to a platform, the system comprising:

a platform having a software services component and an interface component, the interface component having at least one interface for providing access to the software services component for enabling application domain software to be installed, loaded and run in the platform;

an access controller for controlling access to the software services component by a requesting application domain software via the at least one interface, the access controller comprising:

an interception module for receiving a request from the requesting application domain software to access the software services component;

and a decision entity for determining if the request should be granted wherein the decision entity is a security access manager, the security access manager holding access and permission policies; and

wherein the requesting application domain software is granted access to the software services component via the at least one interface if the request is granted.

5. The system according to claim 1, wherein:

the security access manager has a record of requesting application domain software; and

the security access manager determines if the request should be granted based on an identification stored in the record.

Ericsson v. TCL

Majority

Directed to an Abstract Idea?

- Yes; Claim 1 breaks down into the core abstract idea of “an access controller for controlling access” by “receiving a request” and then “determining if the request should be granted”.
- Ericsson’s arguments:
 - Idea of controlling access to resources is not an abstract idea because it does not resemble one previously recognized by the Supreme Court (mathematical algorithm; method of organizing human activity; fundamental economic practice)
 - Supreme Court has explicitly rejected categorical rules. Controlling access to resources is exactly the sort of process that “can be performed in the human mind, or by a human using a pen and paper” (similar to loaning materials to card-holding members at libraries).
 - Claims are not directed to an abstract idea because they “solve the specific computer problem . . . Of controlling app access in resource-constrained mobile phones”.
 - Claims do not mention and are not limited to mobile phones or “resource-constrained environment”. Furthermore, claims do not have specificity required to transform claim. (Specification also does not limit to mobile phones; boilerplate language at end expressly disavows any interpretation limiting its scope only to mobile terminals).

Something More?

- No; Ericsson contends that the “layered architecture” of the invention is the inventive concept, but neither claim recites any architecture at all, let alone layers. Ericsson argues that the analysis should be guided by considering the specification, but “any reliance on the specification in the 101 analysis must always yield to the claim language”, and the claims recite no details that could lead to importing those “necessary elements”.

Ericsson v. TCL



Dissent (Newman):

Directed to an Abstract Idea?

- No; the claims are not merely the abstract idea of controlling access to resources. The claims recite a technological system using a layered architecture that isolates an application domain containing apps from phone services using an interception module. This is an improvement in the operation of computers, not an abstract idea.

Something More?

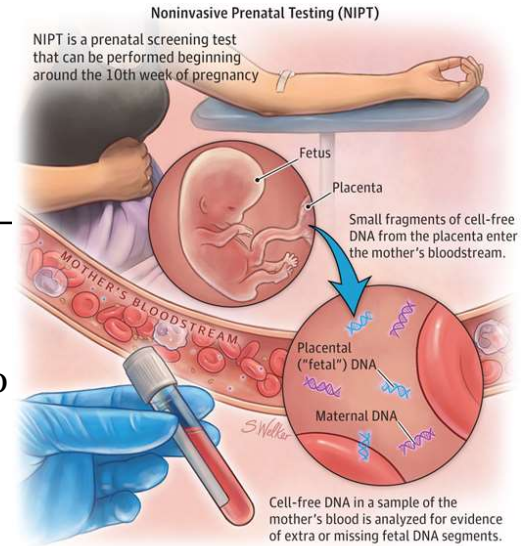
- Yes; a specific solution to a technological problem (layered architecture is a specific implementation of a mobile-phone security system).

Panel majority creates new Section 101 law by requiring all technologic information in the specification to be recited in the claims in order to not be abstract: “This is a new requirement for claims, and not only conflicts with the opportunity to present claims of varying scope, but also conflicts with the principle that claims are intended to be concise statements of the patent invention as distinguished from the prior art”.

Majority also discarded “necessary antecedent and subsequent components” in deciding that the remainder of the claim was directed to an abstract idea.

The final paragraph of the specification (boilerplate language stating that the invention can be varied in many ways without departing from the scope) was used by the panel majority to support the claims being for an abstract idea. This was incorrect and would lead to Section 101 invalidity being imported into virtually all existing patents.

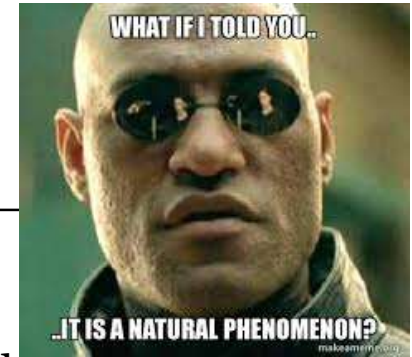
Illumina, Inc. v. Ariosa Diags., Inc., 952 F.3d 1367 (Fed. Cir. 2020)



Factual History

- Directed to **methods of preparing** DNA samples from a pregnant women to analyze for genetic abnormalities fetal DNA circulating in the mother's plasma
- Predicated on two scientific discoveries
 - First, scientists discovered the presence of cell-free fetal DNA in maternal plasma and serum
 - Applied for patent, which claimed **methods for detecting** the fetal DNA in maternal blood
 - Patent held invalid under § 101 for claiming a natural phenomenon (*see Ariosa Diags, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015))
 - Later, the current inventors identified and solved an issue with this method of detection
 - Most (>90%) of extracellular DNA in mother's blood is derived from mother
 - No known way to separate fetal DNA from vast amount of maternal DNA
 - Very difficult to assess genetic abnormalities based on the small amount fetal DNA in blood sample
 - Inventors discovered that fetal DNA was smaller in size (<500 base pairs) than maternal DNA
 - Utilized this discovery to develop a method for enhancing amount of fetal DNA in the sample

Illumina v. Ariosa



Legal Standard (Patent Eligibility Test)

- **Step 1:** Examine whether claims are directed to laws of nature or natural phenomenon
- **Step 2:** If yes, then examine whether the limitations of the claims apart from law of nature or natural phenomenon “transform the nature of the claim into a patent-eligible application”

Analysis (Patent Eligibility Step 1)

- Court identified the natural phenomenon: Fetal cell-free DNA is shorter than maternal cell-free DNA
 - But determined claims were not directed to this phenomenon
- Instead claims directed to: **Methods for preparing** a fraction of cell-free DNA that is enriched in fetal DNA
 - Changes composition of mixture from what occurs naturally
 - Exploits observation that mother’s DNA is shorter than fetal DNA, rather than simply observing it

ILLUMINA v. ARIOSA

• How to reconcile with *Ariosa*?

	Ariosa	ILLUMINA
§ 101 Determination	Ineligible Subject Matter	Eligible Subject Matter
Type of Claims	Diagnostic	Method of Preparation
1st Step	Directed to detecting natural phenomenon	Natural phenomenon exploited, not claimed
2nd Step	Only adds routine and well-understood steps	N/A (Note: found to be routine)
Preemption	No preemption, but insufficient on own to overcome ineligibility	Not examined by majority, but considered in dissent

1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises

amplifying a paternally inherited nucleic acid from the serum or plasma sample and

detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

1. A method for preparing a deoxyribonucleic acid (DNA) fraction from a pregnant human female useful for analyzing a genetic locus involved in a fetal chromosomal aberration, comprising:

(a) extracting DNA from a substantially cell-free sample of blood plasma or blood serum of a pregnant human female to obtain extracellular circulatory fetal and maternal DNA fragments;

(b) producing a fraction of the DNA extracted in (a) by:

(i) size discrimination of extracellular circulatory DNA fragments, and

(ii) selectively removing the DNA fragments greater than approximately 500 base pairs,

wherein the DNA fraction after (b) comprises a plurality of genetic loci of the extracellular circulatory fetal and maternal DNA; and

(c) analyzing a genetic locus in the fraction of DNA produced in (b).

Illumina v. Ariosa

- Court likened the patents-at-issue to methods of preparation claims in *CellzDirect*, rather than naturally-occurring DNA in *Myriad*

Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016)

Assoc. Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013)

– In *CellzDirect*, inventors discovered that some hepatocytes survive multiple freeze-thaw cycles, and patented a process to select for cells that survive the first freeze/thaw cycle

– Federal Circuit held claims patent eligible because claims:

[were] not simply an observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles. Rather, the claims are directed to a new and useful method of preserving hepatocyte cells.”

CellzDirect, 827 F.3d at 1050.

- Similarly, here, inventors also used their discovery to new and useful method to prepare a sample enriched with fetal DNA
- Irrelevant that patents use conventional techniques to selectively remove maternal DNA
 - This only arises if claims are directed to a natural phenomenon (i.e., Step 1 = Yes)

Illumina v. Ariosa

Dissent (Circuit Judge Reyna)

- All asserted patents are invalid under § 101
 - Step 1:** Asserted patent claims are directed to natural phenomenon (i.e., fetal DNA’s relative small size compared to maternal NDA)
 - Majority side-stepped precedent by making unique bucket for “method of preparation” patents, rather than “diagnostic” patents
 - Here, written description supports that only “surprising” aspect of invention is that fetal DNA is shorter than maternal DNA
 - Step 2:** The claimed method fail to transform the natural phenomenon into patent eligible subject matter
 - Aside from this discovery, nothing new or useful about claimed invention
 - Each of the method steps are known and conventional laboratory techniques
 - Preemption:** The claims will tie up future innovation because no skilled artisan would be entitled to rely on the natural phenomenon to isolate cell-free fetal DNA

Claim Construction



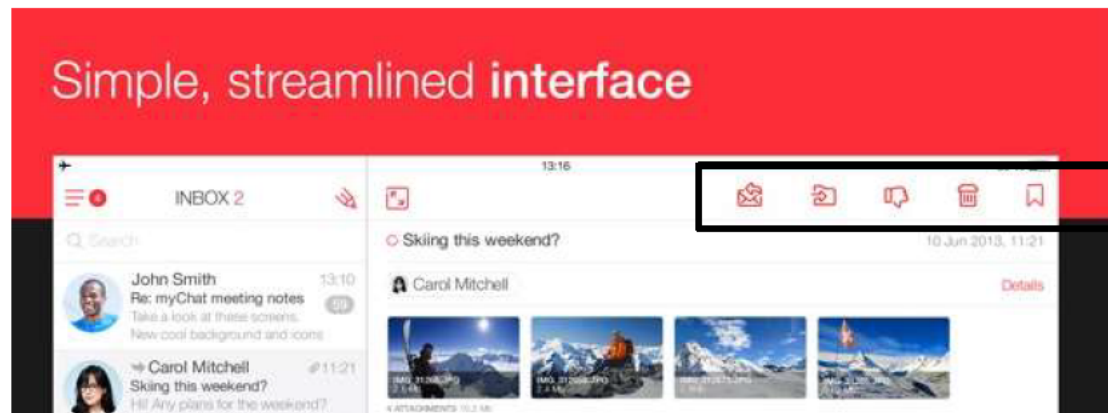
MyMail, Ltd. v. ooVoo, LLC, 934 F.3d 1373 (Fed. Cir. 2019)

Factual/Procedural History

- MyMail sued ooVoo for infringing two patents
 - U.S. Patent No. 8,275,863, “Method of modifying a toolbar”
 - U.S. Patent No. 9,021,070, “Dynamically modifying a toolbar”
- MyMail raised claim construction issue, “toolbar”
- ooVoo filed motion for judgment on pleadings
 - Granted; patent-ineligible under 35 U.S.C. § 101
 - MyMail appealed

Issue

Whether claim construction dispute is a factual issue that must be decided before a dispositive motion on § 101.



MyMail v. ooVoo

Legal Standard

- *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018): Patent eligibility can be decided on a FRCP 12(c) motion only when there are **no outlying factual issues**

Claim Construction Issue

- MyMail argued N.D. Cal. should adopt E.D. Tex.’s construction of “toolbar”
- N.D. Cal. failed to resolve dispute, skipped to § 101 analysis



Held

District court must resolve claim construction disputes before invalidating under § 101.

Vacated and remanded.

Dissent

- “I respectfully dissent from the majority’s decision to vacate a thorough and well-reasoned district court decision based on a claim construction issue that is **little more than a mirage.**”

Amgen Inc. v. Amneal Pharms. LLC, 945 F.3d 1368 (Fed. Cir. 2020)



ANDA case involving Amgen's drug Sensipar.

1. A pharmaceutical composition **comprising**:

- (a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg;
- (b) from about 45% to about 85% by weight of a diluent selected from the group **consisting of** microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrans, and mixtures thereof,
- (c) from about 1% to about 5% by weight of **at least one** binder selected from the group **consisting of** povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof; and
- (d) *from about 1% to 10% by weight* of **at least one** disintegrant selected from the group **consisting of** crospovidone, sodium starch glycolate, croscarmellose sodium, and mixtures thereof,

Wherein the percentage by weight is relative to the total weight of the composition, and wherein the composition is for the treatment of **at least one of** hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

Amgen v. Amneal

Claim History:

- “A pharmaceutical composition comprising an effective dosage amount of a calcium receptor-active compound and at least one pharmaceutically acceptable excipient, wherein” the composition achieved a specific dissolution profile.
- A pharmaceutical composition comprising:
 - (a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg;
 - (b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrans, and mixtures thereof,
 - (c) from about 1% to about 5% by weight of at least one binder; and
 - (d) *from about 1% to 10% by weight* of at least one disintegrant,

Wherein the percentage by weight is relative to the total weight of the composition.

Amgen v. Amneal

District Ct.:

Claim Construction:

Amgen: Markush groups should be open to unrecited elements.

District Ct: “Amgen has not overcome the very strong presumption that the Markush groups for the binder and disintegrant elements are closed to unrecited binders and disintegrants”. (“Consisting of”).

Infringement:

Amneal’s product does not infringe claims because its product does not meet the binder and disintegrant limitations:

- Binder: Amneal uses Opadry Clear YS-1-7006, product containing HPMC (among other elements). HPMC is a listed binder, but Opadry is not.
- Disintegrant: Amneal uses crospovidone, which is a listed disintegrant. However, court found that Amneal’s product does not meet limitation due to claim construction (also included unlisted disintegrant pregelatinized starch).

Piramal’s product does not infringe because it does not meet the binder limitation. Piramal uses pregelatinized starch; Amgen argued that the cold-water-soluble fraction of the starch is equivalent to povidone (listed binder). Court rejected this as barred by PHE (due to Amgen accepting Examiner’s Amendment).

Zydus’s product infringes the asserted claims.

Amgen v. Amneal

Fed Circ. Claim Construction:

- *Multilayer* and *Shire* did not hold broadly that whenever “consisting of” language is present, even when limitation follows “comprising”, all components of an accused product that perform the general function of the particular limitation must meet the requirements of that limitation. Instead, they held that the terms of a particular claim limitation that used “consisting of” language were restricted to members of the Markush group.
- Here, no language in the claim indicating that every binder or disintegrant in the claimed formulation must be within the Markush groups (“at least one” binder or disintegrant “selected from the group consisting of” various excipients does not mean that the only binders in disintegrants in the formulation are those listed in the groups).
- Further supported by “comprising”, which does not foreclose additional optional binders and disintegrants.

Amgen v. Amneal

Holdings:

Amneal:

- Opadry contains HPMC, a listed binder, so provided that Amneal's formulations contains 1%-5% HPMC, formulation literally meets the binder limitation (district court erred by considering whether Opadry was "literally HPMC").

Piramal:

- Amgen's DoE argument is barred by prosecution history estoppel. Two amendments made during prosecution, including accepting Examiner's Amendment. Amgen argues that only the first was adopted for a substantial reason relating to patentability, but if that were true, then the Examiner proposed the Examiner's Amendment for no purpose. Boilerplate language in later documentation after Examiner's Amendment was accepted does not change result.

Zydus:

- District Court did not clearly err in finding pregelatinized starch in Zydus's product functions as a diluent.

Section 112



HZNP Fin. Ltd. v. Actavis Labs. UT, Inc., 950 F.3d 867 (Fed. Cir. 2020)

49. A topical formulation consisting essentially of:
1-2% w/w diclofenac sodium;
40-50% w/w DMSO;
23-29% w/w ethanol;
10-12% w/w propylene glycol;
hydroxypropyl cellulose; and
water to make 100% w/w, wherein the topical formulation
has a viscosity of 500-5000 centipoise.

- Panel Majority (*HZNP Medicines v. Actavis*, 940 F.3d 680 (Fed. Cir. 2019)): District Court did not err in finding that “consisting essentially of” was indefinite. The phrase permits claims to encompass formulations “consisting of only the specified materials and those that do not materially affect the basic and novel properties of the claimed invention”. Those basic and novel properties must be definite, or “consisting essentially of” is indefinite. “Better drying time” was a basic and novel feature, but ambiguous, so “consisting essentially of” was indefinite.
- Denial of petition for rehearing on banc.
- Judges Lourie, Newman, O’Malley and Stoll, dissenting: The panel majority erroneously misconstrued “consisting essentially of” language in evaluating 112 definiteness requirement. “[B]etter drying time is not in the claim, and it is the claims that the statute requires be definite”. “[I]t is the language of the claims that must not be indefinite, not the understanding or clarity of an advantage of the invention”. Therefore, “consisting essentially of” should not render claims that do not recite advantages of an invention indefinite.

Idenix Pharms. LLC v. Gilead Sciences Inc., 941 F.3d 1149 (Fed. Cir. 2019)

Factual/Procedural History

- Idenix holds U.S. Patent No. 7,608,597, “Methods and compositions for treating hepatitis C virus”
- Idenix sued Gilead for infringement, with drug sofosbuvir (Sovaldi®)
 - Jury found for Idenix
 - Gilead filed renewed motion for JMOL on written description, enablement
 - Granted; patent invalid for lack of enablement
 - Both parties appealed



Economic Policy

How an \$84,000 drug got its price: ‘Let’s hold our position ... whatever the headlines’

Curing Hepatitis C, in an Experiment the Size of Egypt

A new approach tested in Egypt could become the blueprint for providing cutting-edge medicines to the poor.

Idenix Pharms. LLC v. Gilead Sciences Inc., 941 F.3d 1149 (Fed. Cir. 2019)

Factual/Procedural History

- Idenix holds U.S. Patent No. 7,608,597, “Methods and compositions for treating hepatitis C virus”
- Idenix sued Gilead for infringement, with drug sofosbuvir (Sovaldi®)
 - Jury found for Idenix
 - Gilead filed renewed motion for JMOL on written description, enablement
 - Granted; patent invalid for lack of enablement
 - Both parties appealed



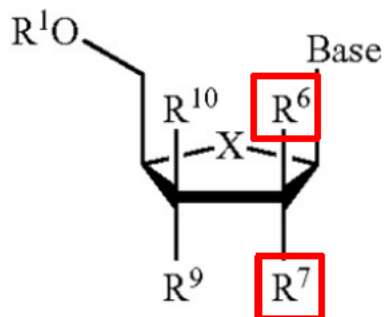
Issue

Whether broad genus claim over molecules to treat Hep C satisfies enablement and written description requirements, when specification describes thousands of variants.

Idenix v. Gilead

Idenix's Invention

In a eleventh principal embodiment the invention provides a compound of Formula XVII, or a pharmaceutically acceptable salt or prodrug thereof:



Key invention is where
 $R^6 = CH_3$ (methyl)

wherein:

Base is a purine or pyrimidine base as defined herein;

R¹ and R² are independently H; phosphate (including mono-phosphate, diphosphate, triphosphate, or a stabilized phosphate prodrug); acyl (including lower acyl); alkyl (including lower alkyl); sulfonate ester including alkyl or arylalkyl sulfonyl including methanesulfonyl and benzyl, wherein the phenyl group is optionally substituted with one or more substituents as described in the definition of aryl given herein; a lipid, including a phospholipid; an amino acid; a carbohydrate; a peptide; a cholesterol; or other pharmaceutically acceptable leaving group which when administered in vivo is capable of providing a compound wherein R¹ or R² is independently H or phosphate;

R⁶ is hydrogen, hydroxy, alkyl (including lower alkyl), azido, cyano, alkenyl, alkynyl, Br-vinyl, —C(O)O(alkyl), —C(O)O(lower alkyl), —O(acyl), —O(lower acyl), —O(alkyl), —O(lower alkyl), —O(alkenyl), chloro, bromo, fluoro, iodo, NO₂, NH₂, —NH(lower alkyl), —NH(acyl), —N(lower alkyl)₂, —N(acyl)₂;

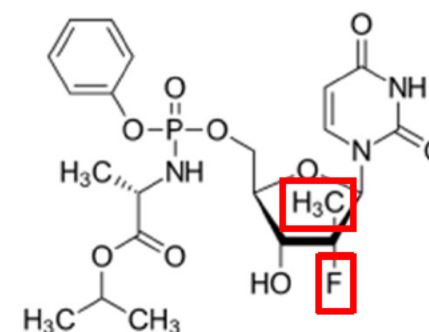
R⁷ and R⁹ are independently hydrogen, OR², hydroxy, alkyl (including lower alkyl), azido, cyano, alkenyl, alkynyl, Br-vinyl, —C(O)O(alkyl), —C(O)O(lower alkyl), —O(acyl), —O(lower acyl), —O(alkyl), —O(lower alkyl), —O(alkenyl), chlorine, bromine, iodine, NO₂, NH₂, —NH(lower alkyl), —NH(acyl), —N(lower alkyl)₂, —N(acyl)₂;

R¹⁰ is H, alkyl (including lower alkyl), chlorine, bromine or iodine;

alternatively, R⁷ and R⁹, or R⁷ and R¹⁰ can come together to form a pi bond; and

X is O, S, SO₂ or CH₂.

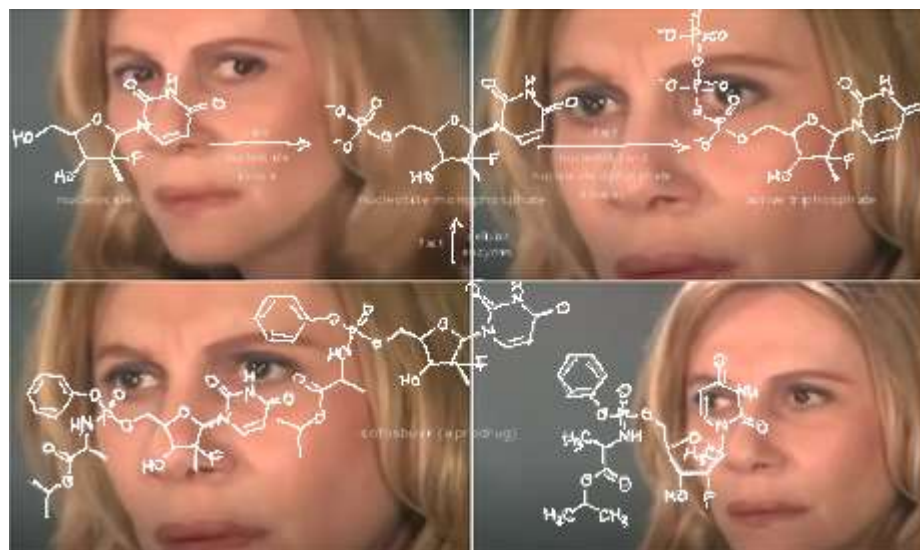
Gilead's Sofosbuvir



Idenix v. Gilead

In re Wands factors for enablement:

1. **Quantity of experimentation**
2. How routine and necessary is experimentation in the field
3. Working examples disclosed
4. Guidance in the patent
5. Nature and predictability of field
6. Level of ordinary skill
7. Scope of claimed invention



Enablement

- “Many, many thousands” of variants disclosed, insufficient guidance
- PHOSITA’s knowledge cannot narrow the field

Idenix v. Gilead

Written description

- Demonstration that inventor was in possession of claimed invention
- Patent does not distinguish effective and ineffective compounds
- Idenix only arrived at working embodiment 1 year after patent application filed

Held

Enablement is not satisfied when thousands of variants are described, and patent does not inform a PHOSITA which species work; written description is not satisfied when patent fails to direct PHOSITA to subset of effective species.

Affirmed for lack of enablement; reversed and found insufficient written description.

Idenix v. Gilead

Dissent

- Enablement and written description
 - Reasonable jury can and did find claimed species sufficiently supported
 - Panel majority looked at, and invalidated patents based on, enablement/written description of *unclaimed* species
- Infringement
 - Majority should have decided infringement question, in Gilead's favor

Section 102: On-Sale Bar



Quest Integrity U.S., LLC v. Cokebusters U.S. Inc., 924 F.3d 1220 (Fed. Cir. 2019)

5 claims held invalid by Dist. Ct based on on-sale bar (summary judgment granted).

- 3 affirmed on appeal.
- 2 reversed and remanded (district court erred in disregarding inventor declarations under the sham affidavit doctrine).

Dist. Ct.:

- Deposition testimony from Robert De Lorenzo, the co-inventor for the patent at issue (and who conducted the furnace inspection for the sale) shows that the sale disclosed the additional claim limitations.
- Later inventor declarations from both De Lorenzo and Phil Bondurant, another co-inventor, which contradict the earlier testimony and state that the sale did not disclose these limitations, were sham affidavits and not considered; thus, no genuine issue of material fact.



Quest v. Cokebusters

Sham Affidavit Doctrine:

- Reviewed under the abuse of discretion standard.
- *Baer v. Chase*, 392 F.3d 609, 624 (3d Cir. 2004): “A party may not create a material issue of fact to defeat summary judgment by filing an affidavit disputing his or her own sworn testimony without demonstrating a plausible explanation for the conflict”.
- Sufficient to create a material dispute of fact:
 - Witness shows they were confused at the earlier deposition or otherwise misspoke.
 - Independent evidence in the record exists to bolster the potentially questionable affidavit.
- Insufficient to create a material dispute of fact:
 - Affiant was carefully questioned on the issue, had access to the relevant information at that time, and provided no satisfactory explanation for the later contradiction.
 - Affidavit is entirely unsupported by the record and directly contrary to other relevant testimony.
 - Affidavit was clearly offered solely to defeat summary judgment.

Quest v. Cokebusters

Holding:

The declarations cannot be dismissed as sham affidavits.

- **Bondurant:**
 - Declaration did not contradict his own earlier testimony, but De Lorenzo’s earlier testimony. Therefore, the district court erred in disregarding his declaration (alongside the reasons it erred in disregarding De Lorenzo’s declaration)
- **De Lorenzo:**
 - De Lorenzo did not merely contradict his earlier testimony, but provided a detailed declaration explaining why his deposition testimony was incorrect.
 - Source code shows that function was still under development after the sale, and was not available for use; De Lorenzo was only given a portion of the source code during the deposition, and not the page with the latest dated comments; and had he been given the latest comment, he would have known that the source code was not commercially available on the date of the sale.
 - Absence of X’s in the Norco Strip Charts shows that the function was not available or used for the sale (had it been used, the code would have instructed the software to display X’s when a bend was detected).
 - Even if the source code were available, the function was “commented out” (unusable by the program).
 - Independent evidence in the record bolstering the declaration (Bondurant’s declaration, testimony from Quest’s experts, source code).

Jury may credit the deposition testimony over the declaration, but not the court on summary judgment.

Section 271(g): Divided Infringement



Syngenta Crop Prot., LLC v. Willowood LLC, 944 F.3d 1344 (Fed. Cir. 2019)

Factual /Procedural History:

- Syngenta sued Willowood entities for copyright and patent infringement
 - 2 Compound Patents for fungicides; 2 Process Patents for preparing fungicides
 - 3 Willowood entities: Willowood China, Willowood USA, & Willowood LLC
- U.S.-based Willowood entities determined to infringe 3 out of 4 Patents
 - Granted SJ of non-infringement of 2 Compound Patents based on concession of importation of fungicide by Willowood USA
 - At trial, found to infringe '761 Patent (burden shifting under § 295)
- Willowood China infringed the '761 Patent
 - Ownership of imported fungicide shifted to Willowood USA before entry into US
- No infringement of '138 Process Patent
 - Syngenta failed to demonstrate all steps of a patented process were practiced by or attributable to Willowood China

Issue: Whether liability for patent infringement under 35 U.S.C. § 271(g) requires that all steps of the patented process performed abroad is practiced by or attributable to a single entity?

NO

Syngenta Crop v. Willowood

Holding: Infringement liability under § 271(g) does not require all steps be performed or attributed to a single entity practicing the patented process abroad

Analysis (Infringement under § 271(g))

- Statutory language supports construction

“Whoever without authority **imports** into the United States **or offers to sell, sells, or uses** within the United States **a product** which is made by a process patented in the United States shall be liable as an infringer.”

35 U.S.C. § 271(g) (emphasis added)

- Act giving rise to infringement involves product NOT practicing the patented process
- Accordingly, whether process is practiced by single entity is immaterial

- Context of statute also supports interpretation

- Infringement liability language of § 271(g) is distinct from § 271(a)

“whoever without authority **makes, uses, offers to sell, or sells any patented invention**, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”

35 U.S.C. § 271(a) (emphasis added)

- Act giving rise to infringement involves the patented invention as a whole
- Accordingly, single entity must practice all process claims to directly infringe

Syngenta Crop v. Willowood

Analysis (Infringement under § 271(g)) (cont.)

- Context of statute also supports interpretation
 - Plain language § 271(f) demonstrates that Congress had appropriate language would attach liability only for acts performed abroad that would be infringing acts in US
 - Congress chose not to use that language when it subsequently drafted § 271(g)
 - Damages provision support construction
 - § 287(b) – Limits damages in manner that makes clear that the act of infringement occurs after a patented process has already been used
- Legislative history further supports construction
 - Senate Report indicates § 271(g) was enacted to prevent circumvention of US process patentee's rights through manufacture abroad and subsequent sales of product in US
 - Also notes that patentee cannot prevent others from using its U.S. process abroad
- Single-entity requirement places undue evidentiary burden
 - Burden shifting provision under § 295 demonstrates Congress recognized burden of proving manufacturing process conducted abroad

Syngenta Crop v. Willowood

Current Status:

- Petition for writ of certiorari is pending
 - Topics for Petition
 - Whether § 271(g) requires all steps of patent process by practiced by or attributable to a single entity?
 - Copyright issue
 - Timing
 - Distributed for conference on May 1
 - Response due on May 26

Preliminary Injunction: Threats of Litigation



Myco Industries v. Blephex LLC, 955 F.3d 1 (Fed. Cir. 2020)

Factual /Procedural History:

- Myco filed action against Blephex seeking DJ of non-infringement and invalidity, and state and federal unfair competition claims
- Myco also filed motion for PI seeking to bar Blephex from:
 - Making false allegations of infringement
 - Threatening litigation against Myco customers
- Court denied Blephex’s motion for supplemental briefing
 - Sought to add federal law requires a showing of bad faith to bar speech
- PI granted
 - Myco showed strong likelihood of success on merits and irreparable harm

Issue: Can courts place prior restraints on free speech related to allegations of patent infringement?

Yes, but bad faith required

Myco Industries v. Blephex LLC

Legal Standard:

When considering a motion for PI, courts must balance:

1. Likelihood of success on merits
2. Irreparable injury for movant
3. Harm to other, if PI granted
4. Public Interest

BUT when PI prevent patentee from communicating its patent rights, must consider if notice properly given

- Requires showing of “**bad faith**”
- Bad Faith = Asserted claim is objectively baseless, such that no reasonable litigant could realistically expect success on the merits

GP Indus., Inc. v. Eran Indus., Inc., 500 F.3d 1369, 1374 (Fed. Cir. 2007)

Myco Industries v. Blephex LLC

- **Holdings:**
 - Court abused discretion by granting PI enjoining patentee's speech without a finding of bad faith
 - Patentee permitted to inform potential infringer of existence of patent if good faith belief in accuracy of information
 - Court made no findings of bad faith
 - Section 287(c) does preclude patentee from alleging infringement by medical practitioner
 - Medical practitioners are not **immune** from infringement
 - Patentee cannot seek remedy against practitioner or related health care entity
 - No evidence of threats against customers
 - Vacated finding of likelihood of non-infringement
 - Court made substantial errors during claim construction

Jury Instructions: Expert vs. Lay Witness



HVLPO2, LLC v. Oxygen Frog, LLC, 949 F.3d 685 (Fed. Cir. 2020)

Factual /Procedural History:

- Patentee filed patent infringement action against accused infringer
- At trial, accused infringer played deposition testimony of a witness not proffered as an expert
 - Witness opined about obviousness of the claimed invention
- Court overruled patentee’s objection that it was an improper expert opinion, but gave limiting instruction to jury
- After jury entered verdict that the claims were obvious, patentee filed motions for JMOL or, in the alternative, new trial
- Court denied motions, and patentee appealed
 - Found no substantial prejudice to patentee, especially in view of limiting instruction

Issue: Is it an abuse of discretion to admit a lay witness’s testimony regarding obviousness, even with a limiting instruction?

YES

HVLPO₂, LLC v. Oxygen Frog, LLC

Analysis (Motion for New Trial)

- Fed. R. Evid. 702(a) allows an **witness qualified as an expert** to provide opinion testimony to help trier of fact understand evidence or determine fact in issue
 - Obviousness judged from perspective of one of ordinary skill in art
 - Precisely the domain of expert witness
- **Holding:** Court's determination that patentee not substantially prejudiced plainly wrong, and it could not be corrected by jury instruction
 - Standard of Review: Abuse of Discretion
 - Witnesses testimony opined on ultimate issue – obviousness
 - Jury instruction cannot correct error that caused substantial prejudice to a party
 - No expert disclosure
 - No *Daubert* motion
 - Only way to cure was to instruct jury to disregard



Copyrights

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PIPLA Year in Review – Copyrights

May 13, 2020

Lisa Bollinger Gehman

Allen v. Cooper (2020)

- Does sovereign immunity shield states from copyright infringement suits?
 - Yes
 - Frederick Allen and his video company, Nautilus Productions, did not prevail in their suit against the State of North Carolina and other state officials

Allen v. Cooper (2020)

- Is the Copyright Remedy Clarification Act, 17 U.S.C. § 501(a) (CRCA), passed in 1990 and which allowed individuals to sue states for copyright violations, constitutional?
 - **District Court and Allen argued no** – Congress clearly stated its intent to abrogate state sovereign immunity and a proper constitutional basis for that abrogation
 - **Fourth Circuit and Supreme Court held yes**
 - Congress' power to provide copyright protection did not authorize it to abrogate the States' 11th Amendment sovereign immunity

Allen v. Cooper (2020)

- Justice Kagan, writing the majority opinion, stated that *Florida Prepaid*, 527 U.S. 627 (1999) “all but rewrote our decision today.”
- This case struck down a similar federal statute, the Patent Remedy Act, that allowed states to be sued for patent infringement
- Article I’s Intellectual Property Clause does not provide a basis for abrogation of sovereign immunity

Allen v. Cooper (2020)

- Section 5 of the 14th Amendment does not allow abrogation in this case because the “congruent and proportional” test was not met:
 - Congress must: (1) show a pattern of unconstitutional infringement with no adequate state remedy and (2) law is tailored to address the due process injury
 - Here, the record of copyright infringement by states was thin and did not justify the CRCA. “Despite undertaking an exhaustive search, [the U.S. Copyright Office] came up with only a dozen possible examples of state infringement ... [and] acknowledged that state infringement is ‘not widespread.’”

Georgia v. Public.Resource.org *(2020)*

- "Why would we allow the official law enacted by a legislature ... to be hidden behind a pay wall?"
 - Question posed by Justice Gorsuch during oral arguments last month

Georgia v. Public.Resource.org (2020)

- Whether annotations made by the Georgia General Assembly in the Official Code of Georgia Annotated (OCGA) are copyrights of the State of Georgia?
 - District Court held yes because the annotations “lacked the force of law”
 - Eleventh Circuit reversed, finding the annotations are government edicts “authored by the People” and not protected (i.e. in the public domain)

Georgia v. Public.Resource.org (2020)

- **Chief Justice Roberts for the majority** – If copyright protection was extended on the basis that the annotations do not have “the force of law,” then economy-class readers would be deprived of important official annotations.
- **Justices Alito, Thomas and Breyer dissented** – 25 jurisdictions with arrangements similar to Georgia’s could be disincentivized to “produce annotated codes altogether,” thereby creating the “economy-class” version of the law the majority found concerning.
- **Justices Ginsberg and Breyer dissented** – The OCGA annotations are not “done in a legislative capacity” and have no force of law, so should not fall under the government edict doctrine.

Google LLC v. Oracle America Inc. (forthcoming from SCOTUS)

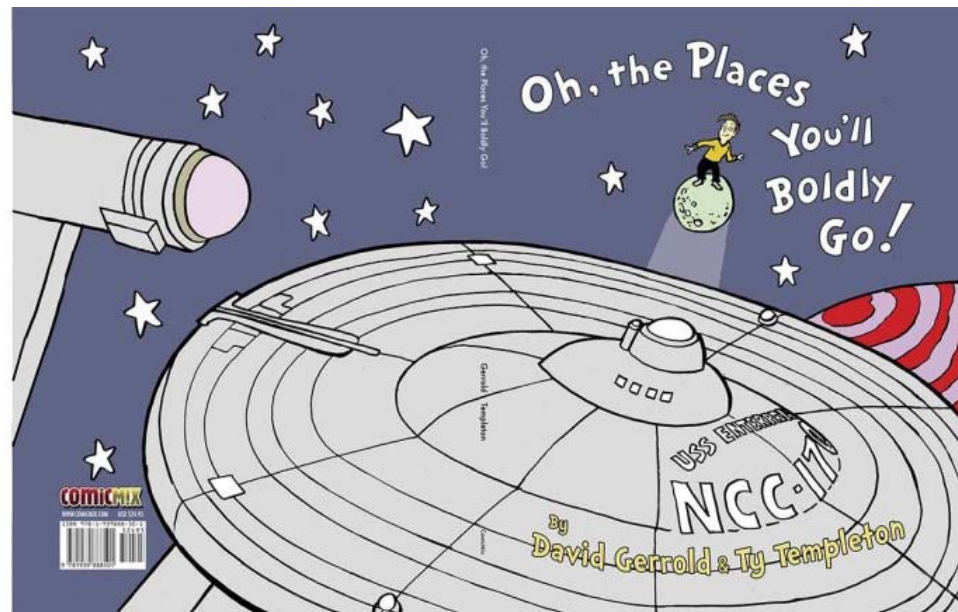
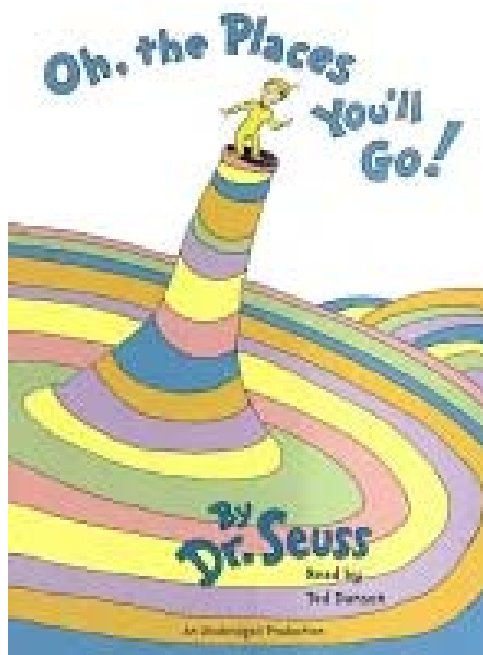
- Dubbed the “the copyright case of the century” – a significant decision for the tech and software industries
 - Facts: When Google implemented its Android OS, it wrote its own programming language based on Oracle’s Java without a license. To facilitate its developers writing the programming for Android OS, Google’s version used the same names, organization, and functionality as Java’s Application Programming Interfaces (APIs).

Google LLC v. Oracle America Inc. (forthcoming from SCOTUS)

- Questions before the Supreme Court:
 - Does copyright protection extend to a software interface?
 - Federal Circuit held yes
 - If so, does Google's use of a software interface in the context of creating a new computer program constitute fair use?
 - Jury said yes, but Fed. Circuit reversed

Dr. Seuss Enterprises, L.P. v. ComicMix LLC (S.D. Cal. 2019)

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Dr. Seuss Enterprises, L.P. v. ComicMix LLC (S.D. Cal. 2019)

- Is *Oh, the Places You'll Boldy Go!* comic book, a mash-up of Dr. Seuss' *Oh, the Places You'll Go!* book and the original *Star Trek* TV series a parody (i.e. fair use) or infringement?
 - District court found ComicMix's book is a parody
 - Dr. Seuss' estate has appealed to the Ninth Circuit

Dr. Seuss Enterprises, L.P. v. ComicMix LLC (S.D. Cal. 2019)

- Fair Use Factors:
 - (1) Purpose and character of use – commercial but “highly transformative”
 - (2) Nature of copyrighted work – highly creative but long and widely published, so only slightly favors Seuss
 - (3) Amount and substantiality of the portion used in relation to the copyrighted work as a whole – does not “copy more than is necessary to accomplish its transformative purpose”
 - (4) Effect of use upon the potential market for the copyrighted work – potential harm to Seuss licensing opportunities presumed but speculative, so neutral

Silvertop Assocs. Inc. v. Kangaroo Mfg. Inc. (3d Cir. 2019)

RASTA IMPOSTA



KANGAROO ITEM 10477



KANGAROO ITEM 10478



Silvertop Assocs. Inc. v. Kangaroo Mfg. Inc. (3d Cir. 2019)

- Does a full-body banana costume qualify for copyright protection?
 - Yes, “[i]n combination, the [Plaintiff’s] costume’s non-utilitarian, sculptural features are copyrightable, so we will affirm the District Court’s preliminary injunction.”
 - Third Circuit relied on the Supreme Court’s recent decision in *Star Athletica v. Varsity Brands*, 137 S. Ct. 1002 (2017), the cheerleader uniform case

Silvertop Assocs. Inc. v. Kangaroo Mfg. Inc. (3d Cir. 2019)

- Separability test
 - (1) can the artistic feature of the useful article be perceived as a two- or three-dimensional work of art separate from the useful article?
 - (2) would the feature qualify as a protectable pictorial, graphic, or sculptural work if imagined separately from the useful article?
 - “[O]ne can ... imagine the banana apart from the costume as an original sculpture. That sculpted banana, once split from the costume, is not intrinsically utilitarian and does not merely replicate the costume, so it may be copyrighted.”
 - “[T]he banana costume’s combination of colors, lines, shape, and length (*i.e.*, its artistic features) are both separable and capable of independent existence, and thus are copyrightable.”

Silvertop Assocs. Inc. v. Kangaroo Mfg. Inc. (3d Cir. 2019)

- Merger Doctrine
 - Does not apply, there are many other ways to make a costume resemble a banana (Rasta provided 20 non-infringing examples)
- *Scenes a Faire* Doctrine
 - Also does not apply, Kangaroo pointed to no specific feature that necessarily results from the costume's subject matter (a banana). A banana costume is likely to be yellow, but it could be any shade of yellow—or green or brown. It is likely to be curved, but it need not be. And it is likely to have ends that resemble a natural banana's, those tips need not look like Rasta's black tips



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Trademarks

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A YEAR IN REVIEW: PIPLA 2020

Trademark Law

Jacqueline M. Lesser

Trademarks 2020

- The bounds of colors and shades as trademarks. *In re Forney*. (Fed. Cir.)
- Priority of rights by a successor. *Moke America LLC v. Moke USA, LLC*
- Record on appeal. *Stratus Networks* (Fed. Cir.)
- Disgorgement of profits. *Romag Fasteners v. Fossil Inc.* SCOTUS
- Whether “.com” can never make a generic term a descriptive mark, subject to a test of acquired distinctiveness. *Booking.com*. Pending decision. SCOTUS

Colors as marks

In re Forney Industries, Fed. Cir. 2020

- Mark in question was a fade out of a range of orange shades used for product packaging for machining tools.



- Whether a multicolored mark can ever be inherently distinctive
- Whether product packaging that employs color can be inherently distinctive in the absence of a shape or border

Fed Circuit Reversal

“We find that the Board erred in two ways: (1) by concluding that a color-based trade dress mark can never be inherently distinctive without differentiating between **product design** and **product packaging** marks; and (2) by concluding (presumably in the alternative) that product packaging marks that employ color cannot be inherently distinctive in the absence of an association with a well-defined peripheral shape or border”

Examples:



Moke America LLC v. Moke USA LLC

2020 USPQ 2d 10400 (TTAB 2020)

- Opposer claims priority based on common law rights obtained through a third party. Those rights were acquired by assignment on November 14, 2016. The Opposer claims its assignor's use went back to at least 1999, and the assignor had received rights that went back to 1974.
- Applicant's application was filed on August 24, 2015, and made use of the mark on August 10, 2015
- Opposition is dismissed for lack of priority of rights.
 - No evidence in the record that the predecessor used the mark before acquisition date.
 - Simply uncorroborated testimony of assignor's use was inadmissible hearsay
 - Records of assignor's sales of product do not support that the mark in question was used on the goods for any date prior to acquisition.

Stratus Networks, Inc. v. UBTA-UBET Commc'ns Inc.,
955 F. 3d 994 (Fed. Cir. 2020)

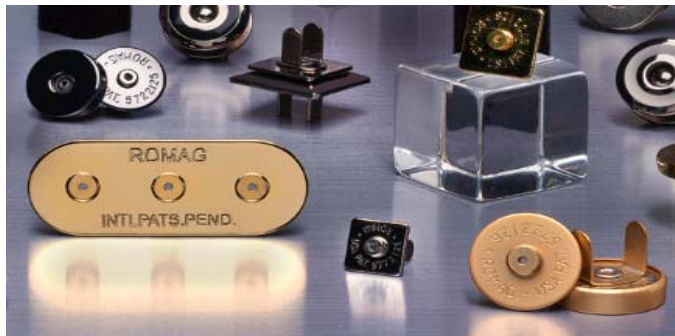
- Section 2d opposition. Two telecommunications providers.
- Marks are:



- Stratus Networks appeals refusal of registration. Alleges that the TTAB failed to give sufficient weight to the sophistication of consumers.
- Six years of coexisting use without confusion discounted where the parties' geographic regions did not overlap.
- The sophistication of consumers did not outweigh the similarity of the marks.
- The Federal Circuit review is whether the Board's factual findings for each considered DuPont factor is "supported by substantial evidence."

Romag Fasteners v. Fossil Inc.

- Resolves a split in the Circuits – in which particular Circuits required a finding of willfulness for an award to be based on a disgorgement of profits.
- The Court, in a unanimous decision, refused to read willfulness into the statute, willfulness is expressly in the statute for actions based on dilution.
- Willfulness is still an element in a likelihood of confusion analysis, but is not a “gatekeeper” to an award of a disgorgement of profits.



Booking.com

Booking.com BOOKING.COM

Pending before SCOTUS

QUESTION PRESENTED

Under the Lanham Act, 15 U.S.C. 1051 *et seq.*, generic terms may not be registered as trademarks. The question presented is as follows:

Whether the addition by an online business of a generic top-level domain (“.com”) to an otherwise generic term can create a protectable trademark.

How did we get here?

- Booking.com B.V. filed series of applications
- Office action refusal on genericness.
- Response that it is not generic for the goods and services but inherently distinctive for the services, in use since 2006.
- The argument is that in this instance, “.com” has significance in the distinctiveness analysis.
- Final refusal on genericness: analysis is: (1) what is the genus? and (2) what does the relevant public understand?
- Applicant concedes a lack of inherent distinctiveness and amends under Section 2(f) and said that since the primary significance of booking.com as a whole, was not for online travel services, the Trademark Office did not meet their burden of proof.

Princeton Vanguard v. Frito Lay
(Fed. Cir. 2015) argument is unavailing:

- Supplemental argument that there has been a change in the law under Princeton Vanguard, the “Pretzel Crisps” case, which reversed a TTAB *inter partes* decision that found that “pretzel” was generic and “crisp” was generic the combination was generic. The Fed. Circuit held that the TTAB applied the wrong standard

“ this court has reiterated that, “[a]n inquiry into the public's understanding of a mark requires consideration of the mark as a whole. Even if each of the constituent words in a combination mark is generic, the combination is not generic unless the entire formulation does not add any meaning to the otherwise generic mark.” *In re Steelbuilding.com*, 415 F.3d 1293 , 1297 (Fed. Cir. 2005). “

District Court Action

- The district court held that the USPTO did not meet their burden that the primary significance of BOOKING.COM was as a generic term for online hotel reservation services.
- The district court held that “booking” was a generic term, but the addition of .com made the combination potentially descriptive and amenable to registration based on acquired distinctiveness.
- Booking.com presented survey evidence overwhelmingly supporting consumer association with a single entity.
- The Fourth Circuit affirms

Oral Argument

- Does public policy weigh against registration of a generic term with a .com modifier – as creating monopoly on a generic top level domain, and unfairly acquiring market power?
- How should the USPTO evaluate generic claims?
- What about the existing registrations that are a “generic.com?”
- Wouldn't booking.com have sufficient rights against counterfeiters through the law of unfair competition, without registration?



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Patents

Recent Developments in Patent Law

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PTAB Proceedings

Claim Construction- PTAB

35 USC § 101

35 USC § 103

PTAB-IPR/PGR

Thryv, Inc. v. Click-To-Call Techs., LP, 206 L.Ed.2d 554 (U.S. 2020)

Holding: 35 U.S.C. § 314(d) precludes judicial review of USTPO application of the 1 year time bar for filing a petition for inter partes review under 35 U.S.C. § 315(b)

There is no appellate review of a decision by PTAB to institute an IPR even when PTAB interprets the meaning of the 1 year time bar for filing a petition requesting an IPR

PTAB-IPR/PGR

Thryv, Inc. v. Click-To-Call Techs., LP, 206 L.Ed.2d 554 (U.S. 2020)

Relevant Statutory Provisions:

35 U.S.C. § 315(b) An inter partes review may not be instituted if the petition...is filed more than 1 year after the petitioner is served with a complaint alleging infringement of the patent.

35 U.S.C. § 314(d) The Determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable

PTAB-IPR/PGR

***Thryv, Inc. v. Click-To-Call Techs., LP*, 206 L.Ed.2d 554 (U.S. 2020)**

- Inventor filed suit against predecessor of Thryv in 2001; that suit was later dismissed without prejudice
- Thryv filed ex parte reexams; the USPTO confirmed patentability of the claims
- Click-to-Call filed suit against Thryv; Thryv filed a petition for IPR; the PTAB 1) instituted the IPR ruling that the dismissed complaint does not trigger 35 U.S.C. § 315(b) and 2) cancelling all the claims
- Click-to-Call appealed and the Fed. Cir. reversed on the time bar issue, holding that time bar determinations are appealable
- Supreme Court reversed (Ginsberg) with Gorsuch dissenting

PTAB-IPR/PGR

Thryv, Inc. v. Click-To-Call Techs., LP, 206 L.Ed.2d 554 (U.S. 2020)

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PTAB-IPR/PGR

***Thryv, Inc. v. Click-To-Call Techs., LP*, 206 L.Ed.2d 554 (U.S. 2020)**

The application of 35 U.S.C. § 315(b) time limit is “closely related to the agency’s decision to whether to institute the inter partes review” and is therefore nonappealable

35 U.S.C. § 314(d) further bars a party from using its appeal from a final written decision to overturn an institution-stage decision

PTAB-IPR/PGR

Facebook, Inc. v. Windy City Innovations, LLC, 953 F.3d 1313 (Fed. Cir. 2020) (joinder)

Arthrex, Inc. v. Smith & Nephew, Inc., 941 F.3d 1320 (Fed. Cir. 2019) – appointment of APJ’s to the PTAB violates the appointments clause (petition for cert filed)

Claim Construction/PTAB

Personalized Media Communs., LLC v. Apple Inc., 952 F.3d 1336 (Fed. Cir. 2020)

Holding: Anticipation and obviousness determination reversed-in-part because the PTAB erred by requiring prosecution history evidence to rise to the level of disclaimer in order to inform meaning of the claim term

Personalized Media Communs., LLC v. Apple Inc., 952 F.3d 1336 (Fed. Cir. 2020)

- Apple filed a petition for, and the PTAB later instituted, an inter partes review of certain claims of U.S. Patent No. 8,191,091
- The PTAB held the instituted claims were unpatentable on anticipation and obviousness grounds
- PMC appealed the final written decision, challenging certain claim constructions
- Reversed-in-part and affirmed-in-part

Claim Construction/PTAB

Personalized Media Communs., LLC v. Apple Inc., 952 F.3d 1336 (Fed. Cir. 2020)

Term at issue is “an encrypted digital information transmission including encrypted information...”

PMC	Apple
includes <i>entirely</i> digital information	includes digital and analog information

Prior art* disclose a transmission including digital and analog information

Claim Construction/PTAB

Personalized Media Communs., LLC v. Apple Inc., 952 F.3d 1336 (Fed. Cir. 2020)

PMC	Apple
includes entirely digital information	includes digital and analog information

Court found that the claims and specification plausibly support both constructions
PTAB held that amendments and statements in prosecution history did not rise to level of a disclaimer of claim scope

Applicant's repeated and consistent remarks during prosecution can define a claim term

Claim Construction/PTAB

Personalized Media Communs., LLC v. Apple Inc., 952 F.3d 1336 (Fed. Cir. 2020)

Reiterates the importance and care that should be taken in drafting amendments and remarks during prosecution

Example of where repeated and consistent prosecution statements aided the patentee...a more narrow term avoided the prior art

35 USC § 101

CardioNet, LLC v. InfoBionic, Inc., 955 F.3d 1358 (Fed. Cir. 2020)

Holding: Claims directed to an improved cardiac monitoring device is not to an abstract idea under 35 USC § 101

35 USC § 101

CardioNet, LLC v. InfoBionic, Inc., 955 F.3d 1358 (Fed. Cir. 2020)

Patent focused on distinguishing between atrial fibrillation and atrial flutter by focusing on variability of the heartbeat

CardioNet filed suit; InfoBionic filed a motion to dismiss under 12(b)(6)

The District Court granted InfoBionic's 12(b)(6) motion and CardioNet appealed

The Federal Circuit reversed

35 USC 101

CardioNet, LLC v. InfoBionic, Inc., 955 F.3d 1358 (Fed. Cir. 2020)

The Court concluded that the claims are not directed to an abstract idea under step 1 of Alice

The District Court improperly 1) assumed the claims are directed to automating known techniques with nothing on the record to support that assumption, and 2) disregarded the written description's recitation of advantages of the invention

Claims are similar to those *Visual Memory LLC. V. Nvidia Corp.* 867 F. 3d 1253 (Fed. Cir. 2017) and *McRo, Inc. V Bandai Namco Games Am. Inc.*, 837 F.3d 1299 (Fed. Cir. 2016)

35 USC § 101

CardioNet, LLC v. InfoBionic, Inc., 955 F.3d 1358 (Fed. Cir. 2020)

Factors considered by the court:

- Claims focused on specific means to improve cardiac monitoring
- Written description consistent with the claimed specific means for improvement
- Dependent claims further specified physical features of operation of the device
- Written description includes number of advantages gained by the claimed elements

35 USC § 103

Hospira, Inc. v. Fresenius Kabi USA, LLC, 946 F.3d 1322 (Fed. Cir. 2020)

Holding: 1) Patent claim is obvious because limitation of no more than a 2% decrease in concentration of a component over time was inherent in the prior art and 2) inherency analysis may rely on data obtained after the priority date of the patent

35 USC § 103

Hospira, Inc. v. Fresenius Kabi USA, LLC, 946 F.3d 1322 (Fed. Cir. 2020) -- Precedex

Patent focused on pharmaceutical composition comprising dexmedetomidine with certain storage stability (< about 2% decrease in concentration)

Hospira filed suit, Fresenius stipulated to infringement and alleged invalidity under 35 USC §103

The District Court held the claim would have been obvious over the prior art—the “about 2% limitation was inherent;

Federal Circuit affirmed

35 USC § 103

Hospira, Inc. v. Fresenius Kabi USA, LLC, 946 F.3d 1322 (Fed. Cir. 2020) – Precedex

Fresenius presented extrinsic evidence of 20 samples, all of which met the “about 2 % limitation”

Hospira argued the stability data was not made in accordance with prior art or with examples from the specification; the Court disagreed because the stability data supported a finding of inherency

35 USC 103

Hospira, Inc. v. Fresenius Kabi USA, LLC, 946 F.3d 1322 (Fed. Cir. 2020)

Extrinsic evidence can be used to demonstrate what is necessarily present in a prior art embodiment even if the extrinsic evidence is not prior art...

Suggests the converse is true--extrinsic evidence including post-priority data that disproves inherency should also be relevant to inherency

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Elections

- Secretary: **Andrew Koopman (RatnerPrestia)**
- Board of Governors: **Thomas Gushue (Volpe and Koenig)**
Joseph Mathew (Offit | Kurman)
Kristel Tupja (Ballard Spahr)
- The current Officers will advance as follows:
 - President: **Touhey Myer**
 - President Elect: **Lesley Grossberg**
 - Vice President: **Joseph Boos**
 - Immediate past President: **Steve Weed**
- The following Officer and Members of the Board will complete their two-year terms:
 - Treasurer: **Melissa Gibson (2019-2021)**
 - Board Member: **Lisa Bollinger Gehman (2019-2021)**
 - Board Member: **Jessica Watkins (2019-2021)**

Conclusion
