Chapter 2

Presentation Slides: 2021 Patent Law Update

ANDREW MASON

Klarquist Sparkman LLP Portland, Oregon

SAMUEL THACKER

Klarquist Sparkman LLP Portland, Oregon

Chapter 2—Presentation Sildes. 2021 Patent Law Opdate

PATENT LAW UPDATE February 18, 2022 Sam Thacker & Andy Mason Klarquist

- S. Ct. Decisions
- Federal Circuit Decisions
- USPTO

S. Ct. Decisions

Minerva v. Hologic – 141 S. Ct. 2298

• Issue: scope of assignor estoppel

Truckai Patent

Assignment of Truckai Portfolio to Hologic

Hologic Seeks, and Receives, Broader Claims Hologic Asserts Broader Claim Against New Truckai Company (Minerva)

4

Minerva v. Hologic – 141 S. Ct. 2298 (2021)

- Assignor estoppel remains a viable shield against certain defenses, but "applies only when the assignor's claim of invalidity contradicts explicit or implicit representations he made in assigning the patent"
 - A doctrine grounded in equity must "stay attached to its equitable moorings"
- No estoppel when
 - "assignment occurs before an inventor can possibly make a warranty of validity as to specific patent claims" (e.g., at beginning of application process)
 - "later legal development renders irrelevant the warranty given at the time of assignment"
 - "a post-assignment change in patent claims can remove the rationale for applying assignor estoppel" (e.g., inventor assigns application not issued patent, and assignee enlarges claim scope at USPTO)

5

Klarquist

Minerva v. Hologic - 141 S. Ct. 2298 (2021)

Practice Tips:

- Be wary of general assignments, e.g., as part of an employment agreement
 - Application-specific assignments minimize risk
- Be wary of post-assignment change in claim scope, e.g., broader continuation claims
 - Post-allowance affirmation by inventor(s), perhaps as part of any patent bonus?

6

United States v. Arthrex - 141 S. Ct. 1970

- Issue: whether PTAB APJs violate the Appointments Clause
- Held:
 - APJs unconstitutional "principal officers" because not appointed by President
 - An inferior officer must be "directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate"
- Remedy: right to Director review of PTAB final written decisions

7

Klarquist

Fed. Cir. Decisions

Overview

- Section 101
 - · Yu v. Apple
 - · CosmoKey v. Duo Sec.
- Section 112
 - · Amgen Inc. v. Sanofi, Aventisub LLC
 - Juno Therapeutics, Inc. v. Kite Pharma, Inc.
- · Design Patent Prior Art
 - In re SurgiSil, L.L.P.
- Serial Post-Grant Challenges
 - In re Vivint, Inc.
- Reasonable Expectation of Success (Obviousness)
 - Eli Lilly & Co. v. Teva Pharms. Int'l GmbH
 - Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.
- Teaching Away (Obviousness)
 - Chemours Company FC, LLC v. Daikin Industries, LTD.
- Pleading Requirements
 - Bot M8 LLC v. Sony Corp. of Am.
- Willful Infringement Standard & Enhanced Damages
 - SRI Int'l, Inc. v. Cisco Sys., Inc.
- Prosecution Laches
 - · Hyatt v. Hirshfeld

Section 101

Current Alice Test:

- First, is the claim "directed to" a patent-ineligible concept, i.e., laws of nature, natural phenomena, and abstract ideas?
- Second, "we consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patenteligible application.

Yu v. Apple – 1 F.4th 1040

(Prost, Taranto) (Newman dissent)

• Key Issue:

Whether a claim that recites a specific hardware configuration may be ineligible under Section 101



11

Klarquist

Yu v. Apple – 1 F.4th 1040

1. An improved digital camera comprising:

a first and a second image sensor closely positioned with respect to a common plane, said second image sensor sensitive to a full region of visible color spectrum;

two lenses, each being mounted in front of one of said two image sensors;

said first image sensor producing a first image and said second image sensor producing a second image;

an analog-to-digital converting circuitry coupled to said first and said second image sensor and digitizing said first and said second intensity images to produce correspondingly a first digital image and a second digital image;

an image memory, coupled to said analog-to-digital converting circuitry, for storing said first digital image and said second digital image; and

a digital image processor, coupled to said image memory and receiving said first digital image and said second digital image, producing a resultant digital image from said first digital image enhanced with said second digital image.

12

Yu v. Apple – 1 F.4th 1040

- D. Ct.: Granted FRCP 12(b)(6) motion to dismiss for lack of patentable subject matter
 - Step 1: "abstract idea of taking two pictures and using those pictures to enhance each other in some way"
 - Step 2: "complete absence of any facts showing that the[] [claimed] elements were not well-known, routine, and conventional"
- · Fed. Cir.:
 - Step 1: claim 1 "directed to a result or effect that itself is the abstract idea and merely invoke[s] generic processes and machinery" rather than "a specific means or method that improves the relevant technology"
 - "the mismatch between the specification . . . and the breadth of claim 1 underscores that the focus of the claimed advance is the abstract idea and not the particular configuration discussed in the specification that allegedly departs from the prior art"o

13

Klarquist

Yu v. Apple – 1 F.4th 1040

- TIP: tie your claims to alleged improvement in spec.
- TIP: claim specific manner for achieving claimed result

14

CosmoKey v. Duo Sec. - 15 F.4th 1091

(Stoll, O'Malley, Reyna) (Reyna Concurrence)

1. A method of authenticating a user to a transaction at a terminal, comprising the steps of:

transmitting a user identification from the terminal to a transaction partner via a first communication channel,

providing an authentication step in which an authentication device uses a second communication channel for checking an authentication function that is implemented in a mobile device of the user,

as a criterion for deciding whether the authentication to the transaction shall be granted or denied, having the authentication device check whether a predetermined time relation exists between the transmission of the user identification and a response from the second communication channel,

ensuring that the authentication function is normally inactive and is activated by the user only preliminarily for the transaction,

ensuring that said response from the second communication channel includes information that the authentication function is active, and

thereafter ensuring that the authentication function is automatically deactivated.

Klarquist

CosmoKey v. Duo Sec. - 15 F.4th 1091

- D. Ct.: 12b6 dismissal for lack of patentable subject matter
 - · claims "directed to the abstract idea of authentication . . . the verification of identity to permit access"
- Fed. Cir.:
 - Step 1: Questioned whether claims directed to abstract idea because of narrow focus and tie to written description, but ... did not resolve because claims cleared step 2 (but see J. Reyna dissent)
 - Step 2: "The '903 patent claims and specification recite a specific improvement to authentication that increases security, prevents unauthorized access by a third party, is easily implemented, and can advantageously be carried out with mobile devices of low complexity."
- Tip:
 - explain the inventive concept/benefit/advantage and don't just recite the result in the claim;
 also provide the why/how

16

Other Section 101 Tidbits

- American Axle S. Ct. CVSG brief forthcoming
 - · Judge Moore dissent at CAFC
 - 6-6 deadlock on CAFC rehearing request
 - Am. Axle Cert. Pet. Reply:

"A patent that poses no threat of improperly tying up a law of nature is not 'directed to' such a law."

- In re Zhu, Fed. Cir. Case No. 2021-1761
 - Remanded upon unopposed motion by USPTO
 - Appellee brief:

"rather than evaluating the claims as though the invention improved computer functionality, the board incorrectly analyzed them as if they used a computer to improve other technology"

17

Klarquist

Section 112

- Amgen Inc. v. Sanofi, Aventisub LLC enablement
- Juno Therapeutics, Inc. v. Kite Pharma, Inc. written description

Amgen Inc. v. Sanofi, Aventisub LLC

987 F.3d 1080 (Fed. Cir. 2021) (Lourie, Prost, Hughes)

Issue:

Enablement of broad, functional pharmaceutical claims

Background:

- · Claims recite functional language for antibodies that bind to and block a specific enzyme
- Specification describes structure of a few possible antibodies, but claims encompass millions of other possible candidates

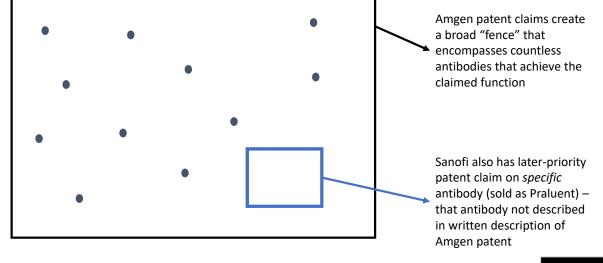
Holding + Reasoning:

- · Invalid for lack of enablement
 - Undue experimentation required to practice the claims' full scope
 - · Unpredictable field; difficult to predict how changes to antibody structure would affect binding
 - Too much trial-and-error experimentation to identify those antibodies that would provide claimed functions / results

19

Klarquist

Amgen Inc. v. Sanofi, Aventisub LLC



20

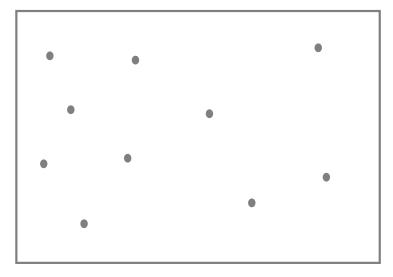
Amgen Inc. v. Sanofi, Aventisub LLC

- Takeaways:
 - · Don't forget the Wands factors
 - Don't forget that the *full scope* of the claim must be enabled, i.e., if you claim a genus, that full genus must be properly supported
 - Make sure claim scope correlates to the embodiments described in the specification

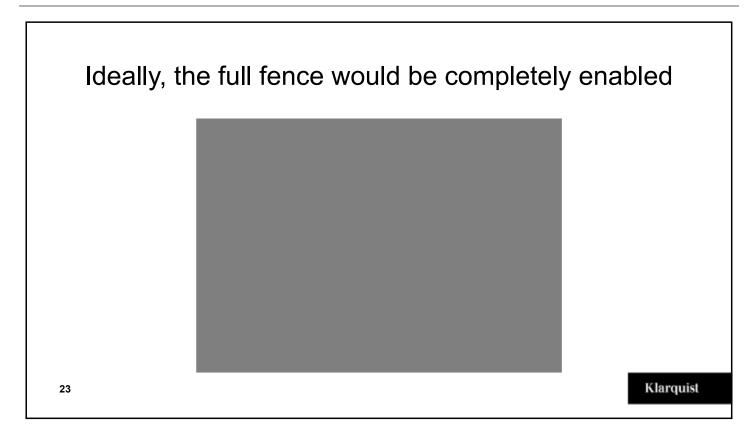
21

Klarquist

Drawing a broad fence around subject matter, without filling in the holes, is not inventing the genus



22

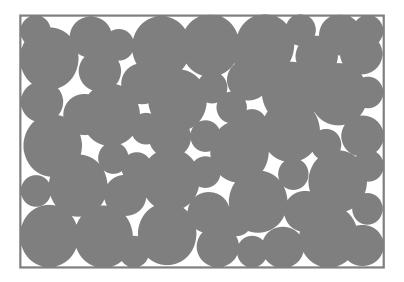


Or, the fence would need to be shrunk to capture only what is enabled



24

Or, the disclosure is further developed so that nearly all the holes are filled in



25

Klarquist

Juno v. Kite

10 F.4th 1330 (Fed. Cir. 2021) (**Moore**, Prost, O'Malley)

- Issue:
 - Written description support for broad, functional genus claims
- Background:
 - Juno's patent claims recite a binding element, but describe it only by its function:
 - · a binding element that selectively binds to a transmembrane protein expressed in certain cancers
 - Claims cover "millions of billions" of possible elements; specification provides only one example
- Holding + Reasoning:
 - · Invalid for lack of written description
 - POSITA unable to determine full scope of claims because
 - Unpredictable field and specification provides no teaching on how to discern the binding elements that would successfully bind to CD19 from those that wouldn't
 - Relatively new field with few examples to help convey what the inventor had possession of

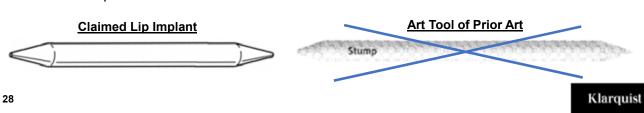
26

Design Patent Prior Art

• In re SurgiSil, L.L.P.

In re SurgiSil, L.L.P. 14 F.4th 1380 (Fed. Cir. 2021) (Moore, Newman, O'Malley)

- - Is the scope of a design patent claim limited to its identified article of manufacture?
- <u>Holding + Reasoning:</u>
 - · Yes, scope of design patent claim is limited to its recited article of manufacture
 - · Claim at issue not anticipated by prior art because prior art is directed to a different article of manufacture (art tool vs. lip implant)
 - Builds on previous 2019 Curver decision



Serial Post-Grant Challenges

• In re Vivint, Inc.

In re Vivint, Inc.

14 F.4th 1342 (Fed. Cir. 2021) (Moore, Schall, O'Malley)

- Issue:
 - Impact of § 325(d) denial of an IPR for abusive filing practices on future Ex Parte Reexams
- Background:

Alarm's 3 serial IPR Petitions all Denied

Alarm's Nearly Identical Reexam Instituted

PTO Denies Vivint's Motion to Terminate Reexam

Vivint Appeals to Fed. Cir.

- Holding:
 - PTO abused discretion by not terminating reexam., after it had previously found nearly identical IPR Petition to be an abuse of process

30

Takeaways

- Beware Section 325(d) in reexaminations could we eventually see the PTO tightening policy on serial reexamination requests?
- Fintiv and Vivint Between a rock and hard place?

31

Klarquist

Reasonable Expectation of Success (Obviousness)

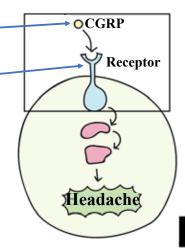
- Eli Lilly & Co. v. Teva Pharms. Int'l GmbH
- Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.

Eli Lilly & Co. v. Teva Pharms. Int'l GmbH

8 F.4th 1331 (Fed. Cir. 2021) (Lourie, Bryson, O'Malley)

- PTAB upheld Teva patents in IPR, finding no reasonable expectation of success that proposed combination would function in a way that met the claims
 - Patent antibody binds to CGRP to treat headache
 - Primary prior art reference bind to receptor to treat headache
 - Secondary prior art reference antibody that binds to exogenously introduced CGRP, not for headache





Klarquist

Eli Lilly & Co. v. Teva Pharms. Int'l GmbH

Holding:

33

 Petitioner did not demonstrate that a POSITA would have reasonably expected to succeed in treating headaches by administering the proposed prior art combination's drug

Reasoning:

- Insufficient evidence that the CGRP-binding drug could cross blood-brain barrier
 - Secondary reference's drug binds to exogenous CGRP
 - Insufficient evidence it could cross the blood-brain barrier (BBB) and reach the site of endogenous CGRP in the synaptic cleft (space between neurons).
- Insufficient evidence that prior art combination's drug could treat headaches w/o crossing the BBB

34

Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.

18 F.4th 1377 (Fed. Cir. 2021) (Moore, Newman, Reyna)

- <u>Issue:</u> reasonable expectation of success for same drug but different dosage?
- •
- Background:

PO's Own Prior Art Label Caps Dosage at <u>X</u> PO Finds Dosage of 2X to be Safe

PO Obtains Patent on Dosage of 2X

Teva Challenges
Patent as Obvious

- Holding + Reasoning:
 - No REOS in being able to safely administer the drug at the higher, claimed dosage since the label explicitly instructed to not exceed a much lower dosage.
 - Affirms PTAB decision to uphold the claims.

35

Klarquist

Takeaways

- REOS matters!
 - Don't shortchange it in IPR Petitions and other post-grant challenges
 - Push back on Examiners who don't adequately address it during prosecution of applications

36

Teaching Away (Obviousness)

• Chemours Company FC, LLC v. Daikin Industries, LTD.

Chemours v. Daikin

4 F.4th 1370 (Fed. Cir.) (Reyna, Newman, Dyk*)

- Prosecution: consider "teaching away" arguments even when not clearly expressed in reference.
- IPR/Lit.: be wary of "teaching away" arguments and, especially in IPR, address those possible arguments with record evidence that is tied directly to the problem being solved.

38

Willful Infringement Standard & Enhanced Damages

• SRI Int'l, Inc. v. Cisco Sys., Inc.

SRI Int'I, Inc. v. Cisco Sys., Inc.

14 F.4th 1323 (Fed. Cir. 2021) (**Stoll**, Lourie, O'Malley)

Issue:

· Willful infringement standard - does it require wanton, malicious, and bad-faith behavior?

Background:

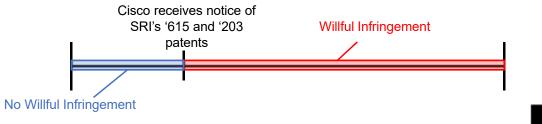
- 2nd time this case reaches the Fed. Cir.
- 1st time, Fed. Cir. reversed D. Ct. finding of willful infringement before notice and appeared to suggest in its remand that willful infringement required wanton, malicious, and bad-faith behavior
- On remand, D. Ct. found no infringement by Cisco after notice.
- SRI appeals.

40

SRI Int'I, Inc. v. Cisco Sys., Inc.

Holding + Reasoning:

- Fed. Cir. clarifies that willful infringement requires only "*deliberate or intentional*" infringement
- Cisco willfully infringed because it actively induced infringement after notice and did not have reasonable invalidity and non-infringement defenses
- Reinstates D. Ct.'s original award of enhanced damages and attorney fees because of Cisco's litigation conduct (pursuing a weak case in an aggressive manner), its large size, its disdain for SRI, and its complete lack of success during SJ and trial



41

Klarquist

Takeaways

- Willful infringement standard clarified: requires only "*deliberate or intentional* infringement"
- Be careful fighting uphill battles
 - Aggressively pushing a "weak case," especially for a large, well-funded client risks enhanced damages and/or attorney fees

42

Pleading Requirements

• Bot M8 LLC v. Sony Corp. of Am.

Bot M8 LLC v. Sony Corp. of Am.

4 F.4th 1342 (Fed. Cir. 2021) (O'Malley, Dyk, Lin)

- · When in doubt, plead in the alternative
- Avoid conclusory allegations that only track claim language
- · Do what the court asks

44

Prosecution Laches

· Hyatt v. Hirshfeld

Hyatt v. Hirshfeld

998 F.3d 1347 (Fed. Cir. 2021) (**Reyna**, Wallach, Hughes)

- Issue:
 - Applicability of prosecution laches to pending applications
- Takeaways:
 - Prosecution laches "applies only in egregious cases of unreasonable and unexplained delay in prosecution"
 - "totality of circumstances" including prosecution activity in related cases and overall delay
 - An unreasonable and unexplained prosecution delay of six years or more raises a
 presumption of prejudice
 - Prosecution laches is exceedingly rare but can be important
 - D. Ct. in *Personalized Media Communications LLC v. Apple Inc.*, relied on *Hyatt* to erase a \$308 million verdict against Apple. Case No. 2:15-cv-01366, (E.D. Tex.)

46

USPTO

Klarquist

IPR Discretionary Denial Under Fintiv & Section 314(a)

- Discretionary denials in view of parallel litigation Fintiv made precedential in May 2020
- 2020 a record year, ~7% of petitions denied under Fintiv
- 2021 slightly lower, ~6.7% of petitions denied under Fintiv
 - · But ... most in first quarter, trending downwards since then
- · Parties adjusted
 - Calculated use of stipulations to not pursue certain prior art invalidity defenses in litigation
 - Use of reexams instead of IPRs (esp. if sued in W.D. Tex.)

48

IPR Discretionary Denial Intersects With Venue



. . .

The negative consequences are most pronounced in the Waco Division of the U.S. District Court for the Western District of Texas. The sole judge in that division schedules very early trial dates for all patent cases assigned to him. Often, these dates prove to be not just unrealistic, but they impossible to fulfill as multiple conflicting trials are frequently scheduled to occur on the same date before the same judge in the same courtroom. However, because PTAB panels interpret Fintiv to require scheduled trial dates to be taken at face value, panels have regularly exercised discretion to deny institution of IPRs in deference to litigation pending before that district.

To be clear, I believe judicial conduct is partly to blame for this situation. Once a case has been

49

Nov. 2, 2021 Letter from Sen. Thom Tillis to Acting Director Hirshfeld

Klarquist

Other Fintiv Tidbits

- No right of appeal. E.g., Mylan v. Janssen (Fed. Cir. March 12, 2021)
- Rule-making? USPTO RFC closed December 3, 2020
- Apple et al. v. Hirshfeld, No. 5:20-cv-06128 (N.D. Cal.)
- US Inventor et al. v. Hirshfeld, No. 2:21-cv-00047 (E.D. Tex.)

50

Resurgence of Ex Parte Reexams

 2020 to 2021, reexamination requests increased by 47% (216→318)



- PTAB petitions dropped ~12% (1513→1333)
- · See Vivint

51

Klarquist

Departure of USPTO Director Iancu

- Pro patent
- Section 101 and 112 Guidance (2019)
- IPR:

52

- Change from BRI to D. Ct. claim construction standard
- · General Plastics cut off serial petitions
- IPR: Fintiv curbed IPR in some venues

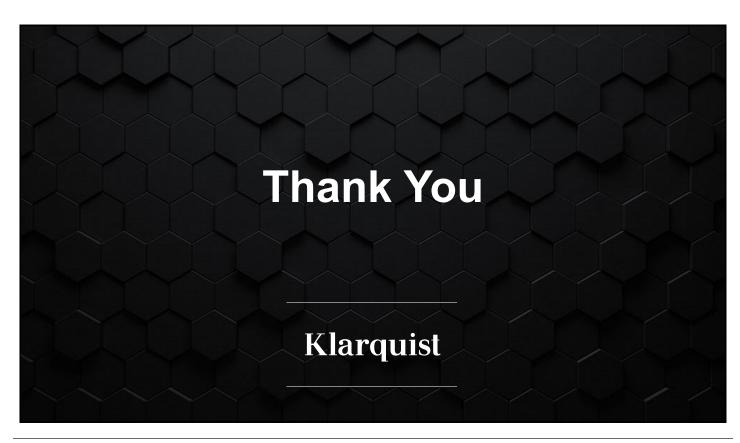


New USPTO Director?

- · Kathi Vidal:
 - · Winston & Strawn
 - Fish & Richardson
 - MSEE
- Nomination process:
 - Nominated October 2021
 - Favorable Judiciary C'ee report on January 13, 2022
 - https://www.congress.gov/nomination/117thcongress/1326



53



Chapter 2—Presentation Slides: 2021 Patent Law Update