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Insights From Leaders In IP Law

Training Academy Session # 3

U.S. Patent Law Case Law Update

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1. Eligibility – 35 U.S.C. § 101

35 U.S.C. 101 Inventions patentable.

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Historically, a very low burden. Then . . .

2010: *Bilski v. Kappos* (561 U.S. 593)
2012: *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* (566 U.S. 66)
2012: *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* (566 U.S. 902)
2014: *Alice Corp. v. CLS Bank Int'l* (573 U.S. 208)
2015: *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* (788 F.3d 1371, 809 F.3d 1282)
2020: *American Axle & Mfg., Inc. v. Neapco Holdings LLC et al.* (967 F.3d 1285, 966 F.3d 1347)

The *Alice* jurisprudence has been characterized as "useless," an "intellectual morass," and "incoherent" *Interval Licensing LLC. v. AOL, Inc.*, 896 F.3d 1335, 1353, 1355 (Fed. Cir. 2018) (Plager, dissenting)

1. Eligibility − 35 U.S.C. § 101

Section 101 in HiTech – Patent Office Analysis

- How Does the US Patent Office Evaluate § 101 Eligibility:
    1. Does the claim fall into a potentially non-patentable judicial exception:
        a. Mathematical Concepts
        b. Methods of Organizing Human Activity
        c. Mental Processes
    2. If the claim does not fall into one of these categories and no "rare circumstance" is present, then the claim should be deemed patent eligible under § 101
    3. If the claim falls into one of the judicial exception categories, then the claims are evaluated to determine if they recite additional elements that integrate the abstract idea into a practical application of that exception. Per 2019 Revised Patent Subject Matter Eligibility Guidance, "[a] claim is not 'directed to' a judicial exception, and thus is patent eligible, if the claim as a whole integrates the recited judicial exception into a practical application of that exception."

1. Eligibility − 35 U.S.C. § 101

Section 101 – Judicial Exceptions

- What are the Judicial Exceptions
  1. Mathematical Concepts – mathematical relationships, mathematical formulas or equations and mathematical calculations
     a. Mathematical Concepts
     b. Methods of Organizing Human Activity
     c. Mental Processes
  2. Methods of Organizing Human Activity – fundamental economic principles or practices, commercial or legal interactions, managing personal behavior or relationships or interactions between people.
  3. Mental Processes – concepts performed in the human mind, including an observation, evaluation, judgment or opinion.

1. Eligibility − 35 U.S.C. § 101

Section 101 – HiTech Case-by-Case Examples

- *Yu v. Apple Inc.*, 1 F.4th 1040 (Fed. Cir. 2021)
  - Claim directed to a digital camera with image sensors, two lenses, converting circuitry to digitize images from the sensors to digital images, an image memory for storing the digital images and an image processor producing a resultant digital image from the first digital image enhanced with the second digital image.

Lenses

Image Sensors

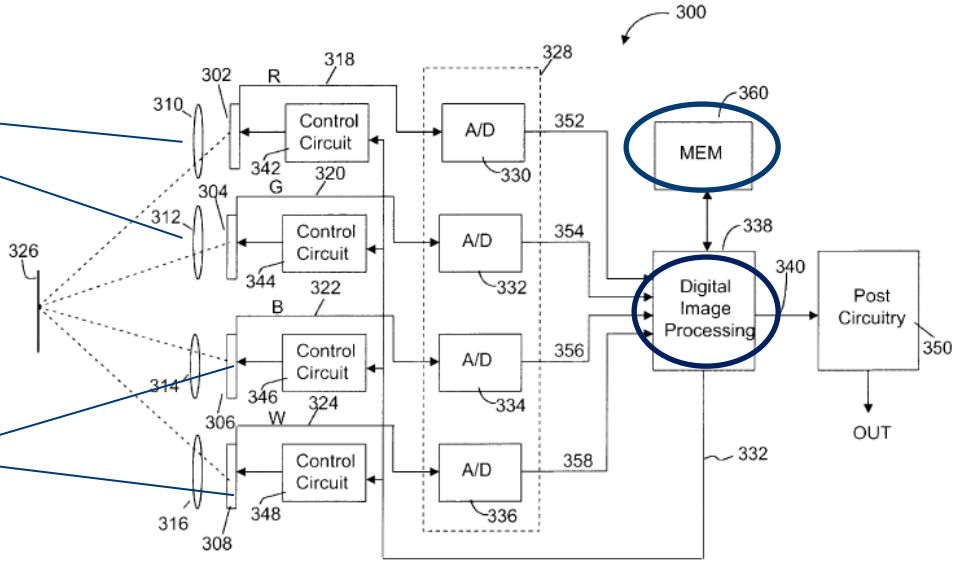


Fig. 3

1. Eligibility − 35 U.S.C. § 101

Section 101 – HiTech Case-by-Case Examples

- *Yu v. Apple Inc.*, 1 F.4th 1040 (Fed. Cir. 2021)
  - *Alice*/*Mayo* Step 1 – The claim is "directed to the abstract idea of taking pictures … and using one picture to enhance the other," so the claim recites "well-understood, routine, conventional components," thereby the claim is ineligible under § 101
  - *Alice/Mayo Step 2 – The claim does not "transform the abstract idea into a patent eligible invention" because the claim "is recited at a high level of generality and merely invokes well-understood, routine, conventional components to apply the abstract idea …."*
  - Dissent – "A device that uses known components does not thereby become an abstract idea …." "The case before us enlarges this instability in all fields, for the court holds that the question of whether the components of a new device are well-known and convention affects Section 101 eligibility, without reaching the patentability criteria of novelty and nonobviousness."

1. Eligibility − 35 U.S.C. § 101

Section 101 – HiTech Case-by-Case Examples

- *Cosmokey Sols. GmbH & Co. KG v. Duo Sec. LLC*, 15 F.4th 1091(Fed. Cir. 2021)
  - Claim directed to a method of authenticating a transaction at a terminal including transmitting user ID, providing authentication through a user mobile device, a criteria for deciding whether authentication is granted or denied based on user response time, ensuring authentication is activated by user for the transaction, ensuring the the response includes information that the authentication function is inactive and ensuring the authentication function is deactivated.
  - *Alice*/*Mayo* Step 1 – The Court determined there was no need to answer the question of whether the claimed invention is a Judicial Exception under Step 1 "because even if we accept the district court's narrow characterization of the '903 patent claims, the claims satisfy *Alice* step two."

1. Eligibility − 35 U.S.C. § 101

Section 101 – HiTech Case-by-Case Examples

- *Cosmokey Sols. GmbH & Co. KG v. Duo Sec. LLC*, 15 F.4th 1091(Fed. Cir. 2021)
  - *Alice*/*Mayo* Step 2 – The Court determined the "claims and the *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."
  - The Court relied heavily on the specification of the patent in the *Alice*/*Mayo* Step 2 analysis – "the specification emphasized the inventive nature of these steps, explaining that 'the complexity of the authentication function can be reduced significantly' because 'the only activity that is required from the user for authentication purposes is to activate the authentication function at a suitable timing for the transaction'"
  - The method of authenticating a transaction at a terminal is patent eligible under § 101

1. Eligibility − 35 U.S.C. § 101

Section 101 in Biotech – The Tortured History of Diagnostic Methods in the Twenty-teens

- The Supreme Court has dealt an especially tough hand to diagnostics.

- Supreme Court in ***Alice*** (2014) set out a 2-step test for patent eligibility:
    1. Whether the claims are "directed to" a law of nature or natural phenomenon; and if yes:
    2. whether the limitations of the claim apart from the law of nature or natural phenomenon, considered individually and as an ordered combination, "'transform the nature of the claim' into a patent-eligible application."

- Added on to ***Mayo*** (2012), in which the Supreme Court held that claims directed to the relationship between the concentration of metabolites in the blood and the likelihood that a drug dose will be ineffective, were directed to a law of nature and therefore unpatentable.

- Since then, the CAFC has generally found claims directed to **methods of treatment to be patent eligible**, but "consistently held **diagnostic claims unpatentable as directed to ineligible** subject matter." *Illumina v. Ariosa Diagnostics*, 952 F.3d 1367, 1371 (Fed. Cir. 2020).

- Two recent cases offer some hope to patent owners here – *Vanda* (2018) and *Illumina* (2020)

1. Eligibility − 35 U.S.C. § 101

***Ariosa* (2015) & *Illumina* (2020) – Adding Sample Prep Step Saves Diagnostic Claims**

- ***Ariosa Diagnostics, Inc. v. Sequenom, Inc***., 788 F.3d 1371 (Fed. Cir. 2015):
  - Method of ***detecting*** cffDNA in blood sample, by amplifying and detecting the cffDNA.
  - Underlying discovery was of cffDNA in maternal blood. Allows analysis for genetic defects.
  - **Invalid**. CAFC held the claim was directed to the natural phenomenon of the presence of cffDNA in maternal blood. Process steps were routine and conventional.
  - "While Drs. Lo and Wainscoat's discovery regarding cffDNA may have been a significant contribution to the medical field, that alone does not make it patentable." *Id*. at 1379-80.
  - **Takeaway**: This is now the baseline test – cannot claim the existence/correlation of biomarkers.

- ***Illumina v. Ariosa Diagnostics***, 952 F.3d 1367 (Fed. Cir. 2020):
  - Method of ***preparation*** of a DNA fraction (i.e., an enriched sample) for analyzing genetic locus
  - **Valid**. Changes the composition of the sample to be different from the naturally occurring fraction.
  - Here, the CAFC credited the enrichment (of biomarkers) step in the claim as one that ***transforms*** the biomarkers in the sample – "prepared using conventional technology in unconventional ways"
  - **Takeaway**: Cannot claim the biomarker, but can claim the method of isolating and enriching.
  - **Drafting Tip**: Add process steps/limitations to the specification and claims. ***But*** these could be designed around to avoid infringement…

1. Eligibility − 35 U.S.C. § 101

<u>*Cellzdirect* (2016) & *Trans Ova* (2020) – Lab techniques are generally safe</u>

- ***Rapid Litigation Management v. Cellzdirect***, 827 F.3d. 1042 (Fed. Cir. 2016): [**Making**]
  - Method of preparing "hepatocytes … capable of being frozen and thawed at least two times," including (a) density gradient fractionation; (b) recovering; and (c) cryopreserving.
  - Underlying discovery was that hepatocytes could survive multiple freeze-thaw cycles.
  - **Valid.** CAFC held claims directed to process for creating a pool of hepatocytes, not the pool itself.
  - Here, it was "a new and useful laboratory technique for preserving hepatocytes. This type of constructive process, carried out by an artisan to achieve 'a new and useful end,' is precisely the type of claim that is eligible for patenting." *Id*. at 1048.
  - **<u>Takeaway</u>**: Again, additional process steps seem to be the differentiating factor.

- ***XY, LLC v. Trans Ova Genetics, LLC***, 968 F.3d 1323 (Fed. Cir. 2020): [**Doing**]
  - Method of operating a flow cytometry apparatus, including creating a fluid stream, executing computer instructions, and using real-time classification
  - Underlying discovery was that manipulating (rotating and scaling/translating) data from a certain parameter would allow better selection of particle populations
  - **Valid**. Claims "'describe in detail a step-by-step method' for accomplishing a physical process. …
  - Like the claims in *Diehr* and *Thales*, claim 1 of the '559 patent incorporates applied mathematics in a purported improvement to an otherwise-known method to yield an improved result." *Id*. at 1331-32.

1. Eligibility − 35 U.S.C. § 101

<u>*Vanda* (2018) & *INO Therapeutics* (2019) – Methods of treatment vs. non-treatment</u>

- *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d. 1117 (Fed. Cir. 2018):
  - Method claims, not that different from those ineligible in *Mayo* – correlating a patient's ability to metabolize a drug with the correct dosage for that patient.
  - **BUT** Vanda claimed "a method for treating a patient" while the claims in *Mayo* were to "a method for optimizing therapeutic efficacy for treatment" of a particular disorder.
  - **Valid**. Court found that Mayo's claims merely recited the natural relationship, but Vanda's "claimed **an application** of that relationship."
  - **<u>Takeaway</u>**: Package claims as methods of treatment. *BUT see below!* (Also, should the preamble matter that much?)

- *INO Therapeutics LLC v. Praxair Distribution Inc.*, 782 Fed. Appx. 1001 (Fed. Cir. 2019):
  - Method of treating neonates with inhaled nitric oxide (INO), by checking for left ventricular dysfunction (LVD), administering to neonates without LVD and excluding those with LDV, to reduce risk of pulmonary edema in neonates with hypoxic respiratory failure.
  - Underlying discovery was that neonate patients with LVD disserved by INO administration.
  - **Invalid!** CAFC held claim was *not* directed to new way of *treating* hypoxic respiratory failure, but instead to *screening* for an adverse condition and *withholding* treatment.
  - **<u>Takeaway</u>**: Method of treatment claims not created equal.
  - **<u>Drafting Tip</u>**: Avoid negative limitations in administration claims?

1. Eligibility − 35 U.S.C. § 101

***BI v. Mylan* (2020) – Nuances to Method of Treatment Claims**

- ***Boehringer Ingelheim v. Mylan Pharms., Inc.***, 803 Fed. App. 397 (Fed. Cir. 2020):
  - Method of treating/preventing metabolic disease in patients for whom metformin is contraindicated (for specific renal impairment reasons), by administering a DPP-IV inhibitor.
  - Underlying discovery was that certain DPP-IV inhibitors are metabolized by the liver rather than the kidney.
  - **Valid**. CAFC held claims patentable under Alice Step 1 and analogized to ***Vanda***.
    - Credited patent owner argument that claims directed to a "method of treating a **specific disease** ([type 2 diabetes mellitus]) for **specific patients** (with renal impairment) using a **specific compound** (linagliptin) at **specific doses** (same dose in patients with renal impairment as in patients with normal renal function) to achieve a **specific outcome**."
  - **Takeaway**: Claims had an active administration step where contraindications existed. Seems hard to square with ***INO Therapeutics***, which held screening-and-withholding-treatment claims invalid. But active administration and greater specificity in dosing seem to have carried the day.

1. Eligibility − 35 U.S.C. § 101

Procedural – Underlying Fact Issues in Section 101 so Fewer Motions to Dismiss

- Courts may consider patent eligibility on the pleadings at the **motion to dismiss** stage.
  - Invalidation rates were initially high in the years immediately after *Alice*, but and have trended downward over time, in part because of two CAFC decisions from 2018.

- ***Berkheimer v. HP Inc.***, 881 F.3d 1360 (Fed. Cir. 2018):
  - "The question of whether a claim element or combination of elements is **well-understood, routine and conventional** to a skilled artisan in the relevant field ***is a question of fact***. Any fact, such as this one, that is pertinent to the invalidity conclusion must be proven by ***clear and convincing evidence***. …
  - Whether a claim recites patent eligible subject matter is a question of law which may contain disputes over underlying facts." *Id*. at 1368 (emphasis added).

- ***Aatrix Software Inc. v Green Shades Software Inc.***, 882 F.3d 1121 (Fed. Cir. 2018):
  - "We have held that patent eligibility can be determined at the Rule 12(b)(6) stage. … This is true ***only when there are no factual allegations that, taken as true, prevent resolving*** the eligibility question as a matter of law." *Id*. at 1125 (emphasis added).
  - Confirmed *Alice* Second Step often involves factual determinations
  - "The district court granted this Rule 12(b)(6) motion without claim construction. We have some doubt about the propriety of doing so in this case…" *Id*.

1. Eligibility − 35 U.S.C. § 101

Procedural – PTO's Guidance is (of course) Not Ultimately Binding

- ***In re Rudy***, 881 F.3d 1360 (Fed. Cir. 2020):
  - "We agree with Mr. Rudy that the Office Guidance is not, itself, the law of patent eligibility, does not carry the force of law, and is not binding in our patent eligibility analysis." *Id*. at 1382.
  - "To the extent the Office Guidance contradicts or does not fully accord with our caselaw, it is our caselaw, and the Supreme Court precedent it is based upon, that must control." *Id*. at 1383 (citing *Cleveland Clinic*).

- ***Cleveland Clinic Found. v. True Health Diagnostics LLC***, 760 F. App'x. 1013, 1021 (Fed. Cir. 2019) (non-precedential):
  - CAFC affirmed that certain diagnostic claims were invalid despite similarity to Example 29 in the (then-current) Office Guidance that described a type diagnostic method claim as valid.
  - "Example 29-Claim 1 is ***strikingly similar*** to claim 1 of U.S. Patent 6,258,540 at issue in ***Ariosa***…" *Id.* at 1020 (emphasis added)
    - "While we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance. And, ***especially regarding the issue of patent eligibility*** and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law." *Id*. (emphasis added).

1. Eligibility − 35 U.S.C. § 101

USPTO Deferred SME Response Pilot

- Can defer responding to SME rejections until earlier of final disposition or withdrawal of all other outstanding rejections.

- Must be “invited” to participate if meeting criteria
  - Criteria: not a continuing application, not made special, first OA states both SME and non-SME rejections, etc.
  - Limited participating examiners; may lead to sparse 101 record; final OA ends it; not all appls. eligible; final OA even if all other rejections resolved.

- Pilot runs from Feb. 1, 2022 to July 20, 2022
  - Notice at 87 Fed. Reg. 776 (Jan. 6, 2022); comments by March 7, 2022

2. Obviousness − 35 U.S.C. § 103

- **All Limitations** − *Univ. of Strathclyde v. Clear-Vu Lighting LLC,* 17 F.4th 155 (Fed. Cir. 2021)
  - "An obviousness determination generally requires a finding that 'all claimed limitations are disclosed in the prior art.'" 17 F.4th at 160 (citing *Par Pharm., Inc. v. TWI Pharms, Inc.*, 773 F.3d 1186, 1194 (Fed. Cir. 2014))
    - Practice Tip: do not let the opponent gloss over *every* claimed limitation

- **No Hindsight** − *Univ. of Strathclyde v. Clear-Vu Lighting LLC,* 17 F.4th 155 (Fed. Cir. 2021)
  - "The inventor's own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill would have followed, as evidenced by the pertinent prior art." 17 F.4th at 165 (quoting *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012))
    - Practice Tip: do not let the opponent use impermissible hindsight

2. Obviousness − 35 U.S.C. § 103

- **Analogous Art** − *Donner Tech., LLC v. Pro Stage Gear, LLC,* 979 F.3d 1353 (Fed. Cir. 2020)
  - Two separate tests define the scope of analogous prior art: (1) whether the art is in the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved. 979 F.3d at 1359 (quoting *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004))
    - Practice Tip: do not forget to question whether the cited art is analogous
  - "Although the dividing line between reasonable pertinence and less-than-reasonable pertinence is context dependent, it ultimately rests on the extent to which the reference of interest and the claimed invention related to a similar problem or purpose. . . . Thus, when addressing whether a reference is analogous art . . . the problems to which both relate must be identified and compared." 979 F.3d at 1359

2. Obviousness − 35 U.S.C. § 103

- **Core 2-Prong Test for Multiple Publications** − *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, No. 2020-22016, 2022 U.S.App. LEXIS 3646 (Fed. Cir. Feb 10, 2022)
  - "A determination of obviousness 'requires [1] finding that a person of ordinary skill in the art would have been motivated to combine or modify the teachings in the prior art and [2] would have had a reasonable expectation of success in doing so.'" **15* (citing *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1382 (Fed. Cir. 2019))
  - Motivation to combine can be found "explicitly or implicitly in market forces; design incentives; the interrelated teachings of multiple patents; any need or problem known in the field of endeavor at the time of invention and addressed by the patent; and the background knowledge, creativity, and common sense of the person of ordinary skill." **16* (citing *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1354 (Fed. Cir. 2013))
  - "We acknowledge, as the dissent notes, that Dr. Smyth did not expressly provide a reason to combine or modify the prior art. . . . But this does not warrant reversal. Since the Supreme Court's decision in *KSR*, we have recognized that an obviousness case does not require expert testimony for every piece of the analysis." **25-26* (noting that "logic, judgment, and common sense" may be used in lieu of expert testimony)

2. Obviousness − 35 U.S.C. § 103

- **Core 2-Prong Test for Multiple Publications** − *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331 (Fed. Cir. 2021)
  - "A finding . . . that a patent challenger has demonstrated a motivation to combine references does not necessarily imply that the challenger has also met its burden of showing a reasonable expectation of success in achieving the claimed [invention]." 8 F.4th at 1344 (citing *Novartis Pharms. Corp. v. West-Ward Pharms. Int'l Ltd.*, 923 F.3d 1051, 1062 (Fed. Cir. 2019))
- **Motivation to Combine** − *Acoustic Tech., Inc. v. Itron Networked Sols., Inc.*, 949 F.3d 1366 (Fed. Cir. 2020)
  - Can come from "the knowledge of those skilled in the art, from the prior art reference itself, or from the nature of the problem to be solved. . . . testimony [is] insufficient where, for example, the testimony consist[s] of conclusory statements that a skilled person *could* combine the references, not that they *would* have been motivated to do so." 1375
- **Motivation to Combine** − *Intel Corp. v. Qualcomm Inc.*, No. 2020-1664, 2021 U.S. App. LEXIS 38340 (Fed. Cir. Dec. 28, 2021) [21 F.4th 784]
  - "we agree that 'simultaneous advantages and disadvantages . . . do not necessarily obviate motivation to combine.'" *19-20 (quoting *Medichem, S.A. v. Rolabo, S.L.*, 427 F.3d 1157, 1165 (Fed. Cir. 2006))

2. Obviousness − 35 U.S.C. § 103

- **Reasonable Expectation of Success** − *Teva Pharms. USA, Inc.*, v. Corcept Therapeutics, Inc., 18 F.4th 1377 (Fed. Cir. 2021)
  - "The reasonable-expectation-of-success analysis must be tied to the scope of the claimed invention. Here, claim 1 of the '214 patent requires safe administration of a specific amount of mifepristone, 600 mg per day. . . . Thus, the Board was required to frame its reasonable-expectation-of-success analysis around that specific dosage of mifepristone. To be clear, this does not mean Teva was required to prove a skilled artisan would have precisely predicted safe co-administration of 600 mg of mifepristone. Absolute predictability is not required. . . . But Teva was required to prove a reasonable expectation of success in achieving the specific invention claimed, a 600 mg dosage." 18 F.4th at 1381. "Because there was no expectation of success for any dosage over 300 mg per day, there was no expectation of success for the specific 600 mg per day dosage." *Id*.
    - Practice Tip: require opponent to link alleged expectation of success to *specific attributes* of the invention

2. Obviousness − 35 U.S.C. § 103

- **Teaching Away** − *Adept Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, No. 2020-22016, 2022 U.S.App. LEXIS 3646, (Fed. Cir. Feb 10, 2022)
  - Reference teaches away if a person of ordinary skill in the art would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. *30-31 (citing *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009))
  - "But the corollary is equally true and particularly fitting here: a reference does not teach away if a skill artisan, upon reading the reference, would *not* be 'discouraged from following the path set out in the reference,' and would *not* be 'led in a direction divergent from the path that was taken by the applicant." **31*.
    - Practice Tip: explain *why* they would have been discouraged and *why* they would have taken a path different from the applicant

2. Obviousness − 35 U.S.C. § 103

- **Overlapping ranges** − *Almirall, LLC. v. Amneal Pharms. LLC*, No. 2020-2331, 2022 U.S.App. LEXIS 6416, (Fed. Cir. Mar. 14, 2022)
  - **PTAB decision**: reference "discloses a range for each of the various components of the composition that either fully encompasses or overlaps/abuts the ranges and amounts for those components recited in the challenged claims, and this is sufficient to create a presumption of obviousness." **11*.
  - **Patentee**: no single reference discloses all of the claimed ranges. *Id*.
  - **CAFC**: Absent evidence indicating something special or critical about the claimed range, an overlap suffices to show that the claimed range was disclosed in − and therefore obvious in light of − the prior art. "A presumption of obviousness does not shift the burden of persuasion to the patentee to prove nonobviousness, but a presumption establishes that 'absent a reason to conclude otherwise, a factfinder is justified in concluding that a disclosed range does just that − discloses the entire range.'" **13* (citing *E.I. du Pont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1008 (Fed. Cir. 2018)). "this case does not depend on overlapping ranges. It is simply a case of substituting one known gelling agent for another. Each may be effective at a different concentration in different formulations, but that is just a property of the particular known material, subject to conventional experimentation." **15*.

2. Obviousness – 35 U.S.C. § 103

- **Objective Indicia of Nonobviousness** ("Secondary Considerations") – *Teva Pharms Int'l v. Eli Lilly & Co.*, 8 F.4th 1349 (Fed. Cir. 2021)
  - Patentee entitled to rebuttable presumption of nexus "if the patentee shows that the asserted evidence is tied to a specific product and that the product 'is the invention disclosed and claimed.'" 8 F.4th at 1360 (citing *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) and quoting *Demaco Corp. v. F. Von Langsdorff Licensing, Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988))
  - Presumption applies "when the patentee shows that the asserted objective evidence is tied to a specific product and that the product 'embodies the claimed features, and is coextensive with them.'" 8 F.4th at 1360 (citing *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) and quoting *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000)).
  - Degree of correspondence falls along a spectrum. Perfect correspondence not needed, but the patentee must demonstrate "that the product is essentially the claimed invention." 8 F.4th at 1361 (quoting *Fox Factory*, 944 F.3d at 1374)
  - "We have never held that the existence of one or more unclaimed features, standing alone, means nexus may not be presumed." *Fox Factory*, 944 F.3d at 1374
  - "to the extent the Board announced a bright-line rule that the presumption of nexus does not apply if any unclaimed feature materially affects the functioning of a product that is alleged to be coextensive, we agree with Teva that the Board erred." 8 F.4th at 1361

3./4. Written Description and Enablement – 35 U.S.C. § 112(a)

- 35 USC § 112(a) - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.
- Written Description Requirement – "[T]he 'essential goal' .. is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker,* 559 F.2d 588, 592 n.4 (C.C.P.A. 1977).
- Enablement Requirement – Requires "that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way." M.P.E.P. § 2164.
- The enablement requirement of 35 U.S.C. 112(a) is separate and distinct from the written description requirement. *Vas-Cath, Inc. v. Mahurkar,* 935 F.2d 1555, 1563 (Fed. Cir. 1991) ("the purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'").

3. Written Description − 35 U.S.C. § 112(a)

Juno v. Kite (Fed. Cir. Aug. 26, 2021) – Further Blow to Functional Genus Claims

- Juno sued Kite on claims directed to cancer immunotherapy technology

- **DCT (C.D. Cal.)** – Jury found claims not invalid for written description or enablement, willful infringement; Judge denied JMOL; result was a HUGE award of $1.2 billion in damages
- **CAFC (3-0)** – reversed, found **no written description**

- Specification must reasonably convey that inventors "had **possession** of the claimed subject matter"
- Written description is a **question of fact** – reviewed under "substantial evidence" standard.

- **Here**, two sets of claims:
- (1) two that broadly claimed ***any* scFv** (single-chain antibody variable fragment) for binding ***any* target**, for which the specification disclosed **2 working examples**, *Slip Op., 9*; and
- (2) two that were limited to scFv's that bind to a specific target (CD19), but specification "provides no details about any CD19-specific scFv" *Id.* at 16.

- BOTH lacked written description. CAFC found that the patent "does not disclose structural features common to the members of the genus to support that the inventors possessed the claimed invention." *Id*. at 13.

3. Written Description − 35 U.S.C. § 112(a)

- **CAFC's holdings:**
- "To satisfy the written description requirement, the patent needed to demonstrate to a skilled artisan that the inventors possessed and disclosed in their filing the particular species of scFvs that would bind to a **representative number of targets**." *Id*. at 10.
- "But, the specification provides no means of distinguishing which scFvs will bind to which targets." *Id*. at 11.

- **Key Quote**: "It is not fatal that the amino acid sequences of these two scFvs were not disclosed as long as the patent provided other means of identifying which scFvs would bind to which targets, such as common structural characteristics or shared traits. But this patent provides nothing to indicate that the inventors possessed the full scope of the genus that they chose to claim." *Id*. at 11.

- **Takeaway**: Court cited ***Idenix*** *Pharms. LLC v. Gilead Scis., Inc*., 941 F.3d 1149, 1164 (Fed. Cir. 2019) and ***AbbVie*** *Deutschland GmbH v. Janssen Biotech, Inc*., 759 F.3d 1285, 1301-03 (Fed. Cir. 2014) in reaffirming that functional similarities alone will not satisfy written description absent "**an established correlation between the structure and the claimed function**."

4. Enablement − 35 U.S.C. § 112(a)

***Amgen v. Sanofi (Fed. Cir. 2021*) – Enablement for Genus/Species, Antibodies**

- Claims directed to antibodies that bind to PCSK9 protein (thereby regulating LDL cholesterol)
- Antibodies claimed by function – all antibodies binding to specific sites (residues) on PSCK9

- **Enablement challenge –**
- Amgen's specification did not enable full scope, required "**undue experimentation**"

- **DCT (D. Del.) –** Jury found he claims enabled, but Judge Andrews found lack of enablement on JMOL
- **CAFC affirmed** 3-0 (Feb. 11, 2021) and denied *en banc* rehearing (June 21, 2021) – **claims invalid**

- ***Wands*** (1988) factors – "the 'go to' precedent for guidance on enablement." *Amgen*, 987 F.3d at 1085.
  - "1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Wands*, 858 F.2d at 737.

- Focus is the scope of the claims:
  - "In particular, it is important to consider the quantity of experimentation that would be required to make and use, **not only the limited number of embodiments** that the patent discloses, but also **the full scope of the claim**." *Amgen*, 987 F.3d at 1086.

4. Enablement – 35 U.S.C. § 112(a)

- **Takeaway**: "While **functional claim limitations** are not necessarily precluded in claims that meet the enablement requirement, such limitations **pose high hurdles** in fulfilling the enablement requirement for claims with broad functional language." 987 F.3d at 1086.

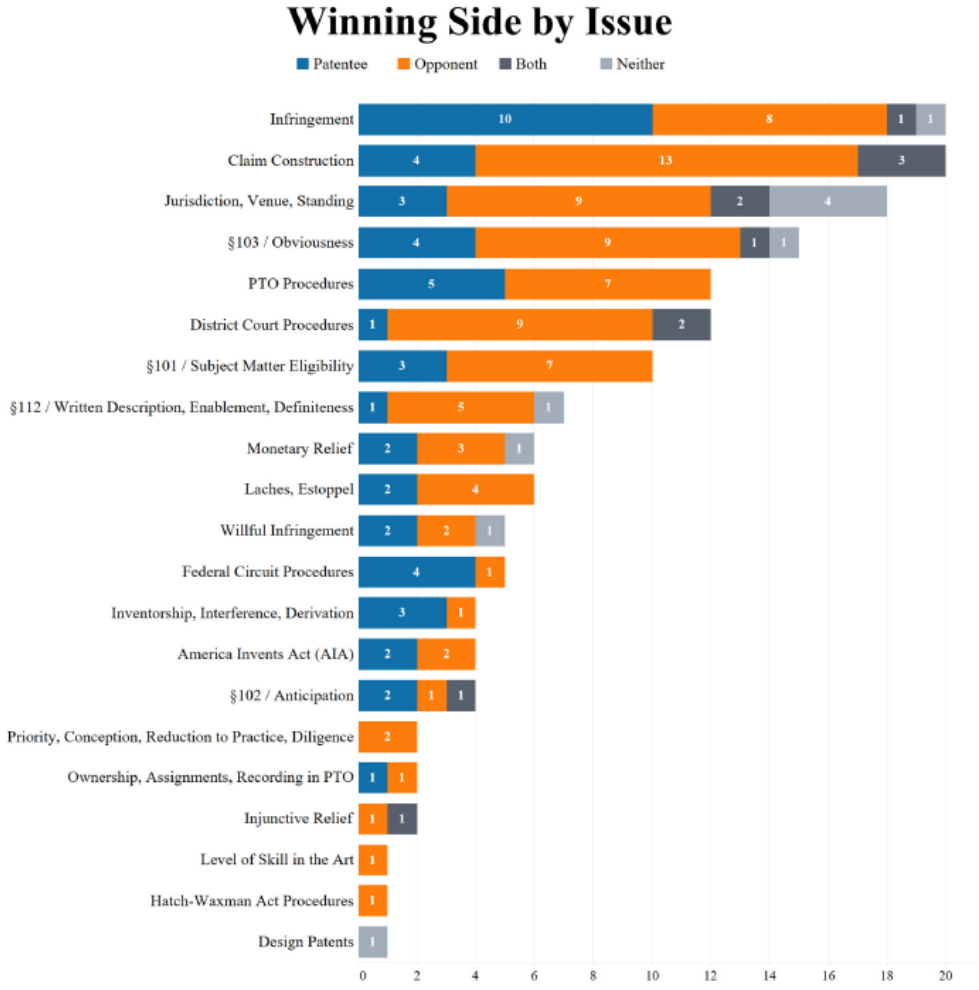
- "the use of broad functional claim limitations **raises the bar** for enablement…" *Id*. at 1087.

- "[W]e are not concerned simply with the number of embodiments but also with their functional breadth. Regardless of the exact number of embodiments, it is clear that the **claims are far broader in functional diversity than the disclosed examples**." *Id*. at 1087.

- **Key for drafters**: "The binding limitation is itself enough here to require undue experimentation." Id. at 1087.

    - Consider adding prophetic examples, constructive reduction to practice
    - Disclose and claim separate species in your genus claims
    - Structure, structure, structure

5. Claim Construction and Infringement



Source: Gibson Dunn 2020/2021 Federal Circuit Year in Review

5. Claim Construction and Infringement

- **Preambles** – *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH,* 8 F.4th 1331 (Fed. Cir. 2021)
  - "there is no 'litmus test' for determining whether a preamble is limiting. . . . Rather, 'whether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent.'" 8 F.4th 1340 (quoting *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003))
  - "The claims in this case are directed to methods, and more specifically to methods of using a composition for a specific purpose. . . . while there is no bright-line rule for determining whether a preamble is limiting, we have generally construed statements of intended purpose in such method claims as limiting." 8 F.4th 1340

5. Claim Construction and Infringement

- **Intrinsic Evidence Is Key** – *Genuine Enabling Tech. LLC. v. Nintendo Co., Ltd.*, No. 2020-2167 (Fed. Cir. Apr. 1, 2022)
  - "This court has long 'emphasized the importance of the intrinsic evidence in claim construction' while also 'authorizing district courts to rely on extrinsic evidence' in certain scenarios." slip op. at 10-11 (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc))
  - "Expert testimony . . . may be useful in claim construction . . . . However, expert testimony may not be used to diverge significantly from the intrinsic record." slip op. at 11
  - "Accordingly, the intrinsic record 'must be considered and where clear must be followed.'" slip op. at 12 (quoting *Mantech Env't Corp. v. Hudson Env't Servs., Inc.*, 152 F.3d 1368, 1373 (Fed. Cir. 1998))
- **Prosecution Disclaimer** – *Genuine Enabling Tech. LLC. v. Nintendo Co., Ltd.*, No. 2020-2167 (Fed. Cir. Apr. 1, 2022)
  - "The doctrine of prosecution disclaimer 'precludes patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.' . . . For a statement during prosecution to qualify as a disavowal of claim scope, it must be 'so clear as to show reasonable clarity and deliberateness,' and 'so unmistakable as to be unambiguous evidence of disclaimer.'" slip op. at 13
  - Practice Tip: avoid or use disclaimer to your advantage; be clear and deliberate

5. Claim Construction and Infringement

GSK v. Teva (Fed. Cir. 2020 & 2021) **– (Non)-infringement through skinny labeling**

- Carve-outs are used to avoid infringement of method patents for drugs with multiple approved uses. Generics will "carve out" the patented method from its proposed drug label, making it a so-called "**skinny label**."
- This deals with **induced infringement**, since prescribing doctors are the direct infringers of method claims.

- **Here**, Teva initially had a skinny label started in 2007 but was required by the FDA to add the carved-out method back into the label in 2011.
  - GSK sued arguing induced infringement for both the skinny label period and the full label period.
- **DCT (D. Del.)** – Jury found infringement for both periods, awarded $235 million. ***But*** Judge Stark granted JMOL to Teva.
  - Credited Teva's argument about following FDA procedures
  - Also found that GSK had shown no evidence that Teva's label caused the doctors to prescribe for the patented method and therefore infringe.

- **CAFC** original panel decision on Oct. 2, 2020 reinstated the jury verdict. It was a 2-1 decision that included a spirited dissent from Judge Prost.
  - Much outcry ensued, because carve-outs are an established practice.
- CAFC granted **rehearing** on Feb. 9, 2021, **vacated** the original decision, issued a new precedential decision on Aug. 5, 2021 – still finding GSK liable for induced infringement…

5. Claim Construction and Infringement

- New Aug. 5, 2021 decision was still 2-1, still has a long dissent from Judge Prost, still finds Teva liable for infringement – so what changed and why the rehearing?
  - Rehearing was granted in part to address outcry from industry/amici over the skinny label practice

- Panel majority stressed that this (precedential!) decision is limited to the facts of the case
  - Deference to jury-found facts
  - Here, the jury had looked beyond the drug label, at Teva press releases and marketing materials, to find intent to induce infringement

- **Key Takeaway**: Confirmed the current understanding of skinny label / carve-out practice, as outline in an amicus brief submitted by Novartis:
  - "Generics could be held liable for actively inducing infringement if they marketed a drug with a label describing a patented therapeutic use or if they took active steps to encourage doctors or patients to use the drug in an infringing manner. But generics could not be held liable for merely marketing and selling under a 'skinny' label omitting all patented indications, or for merely noting (without mentioning any infringing uses) that FDA had rated a product as therapeutically equivalent to a brand-name drug." *Slip Op. at 10*.

6. Markush Rejections

- Recently becoming frequent, especially in the life sciences
- "A 'Markush' claim recites a list of alternatively useable members." M.P.E.P. § 803.02 (citing *In re Harnisch*, 631 F.2d 716, 719-20 (C.C.P.A. 1980)) "The listing of specific alternatives with a Markush claim is referred to as a Markush group." M.P.E.P. § 803.02

> Thus, a Markush grouping is ordinarily proper if all the members of the group belong to a recognized class (whether physical, chemical, or art recognized) and are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed invention, and it is clear from their very nature or from the prior art that all members possess this property.

Ex parte Lambrechts, Appeal No. 2020-006186, p. 6 (P.T.A.B. mailed Mar. 10, 2021)

- Take home: grouping is acceptable if its members: (1) belong to a recognized class; and (2) are disclosed in the Specification as having a common property or function.
- "Whether a Markush group is proper depends on the particular facts at issue and 'must be decided on a case-by-case basis.' MPEP § 706(y)(IV)." *In re Buyyarapu*, Appeal No. 2018-006665, p. 3 (P.T.A.B. mailed Mar. 19, 2019)

6. Markush Rejections

- *In re Buyyarapu*, Appeal No. 2018-006665, pp. 4-5 (P.T.A.B. mailed Mar. 19, 2019) − reversing an improper Markush rejection because the markers were selected out of a larger set of identified markers, were physically located near each other in a particular region, were located on the same chromosome, and shared a use

- *In re Zeigerson*, Appeal No. 2017-998749, pp. 4-5 (P.T.A.B. mailed Dec. 10, 2018) − reversing an improper Markush rejection because the claimed species were all useful in the same way

- *In re Narva*, Appeal No. 2018-006168, pp. 3-4 (P.T.A.B. mailed Apr. 15, 2019) − reversing an improper Markush rejection because all of the sequences shared the common use of silencing ROP proteins

7. Assignor Estoppel

***Minerva v. Hologic* (2021) – Upheld but Limited Assignor Estoppel**

Assignor estoppel generally limits an inventor's ability to assign a patent to another for value and later contend in litigation that the patent is invalid.

- In *Minerva*, the Supreme Court upheld the doctrine of assignor estoppel, but limited its application:
  - "The doctrine applies when, but only when, the assignor's claim of invalidity contradicts explicit or implicit representations he made in assigning the patent."
  - "The doctrine applies only when an inventor says one thing (explicitly or implicitly) in assigning a patent and the opposite in litigating against the patent's owner."
  - "[A]bsent that kind of inconsistency, an invalidity defense raises no concern of fair dealing—so assignor estoppel has no place."

When assignor estoppel likely does ***not*** apply:

- some claim construction arguments, including using prior art to support a narrow construction
- "when the assignment occurs before an inventor can possibly make a warranty of validity as to specific patent claims" (e.g., employee assigns patent rights in any future inventions the employee develops)
- "when a later legal development renders irrelevant the warranty given at the time of assignment" (e.g., the governing law changes "so that previously valid patents become invalid")
- "a change in patent claims [] can remove the rationale for applying assignor estoppel"
  - Arises most often when an inventor assigns an application, rather than an issued patent

8. Patent Term Adjustment ("PTA")

- Patent Term Adjustment is the potential extension of the term of a US patent for certain delays by the US Patent Office in processing a patent application (35 U.S.C. § 154(b)), such as:
    - 1st Action by Patent Office >14 months after filing
    - Response > 4 months after Office Action response
    - Response > 4 months after appeal or Court decision
    - Issue > 4 months after payment of issue fee
    - Pending > 3 years, but excluding RCE, Interference/Derivation, Secrecy Order, review on appeal, delays by Applicant
- *Supernus Pharms., Inc. v. Iancu,* 913 F.3d 1351, 1359 (Fed. Cir. 2019) "The USPTO cannot . . . count as applicant delay any period of time during which there were no efforts in which the applicant could have engaged to conclude prosecution of the patent." Filing of a Supplemental Information Disclosure Statement after filing a Request for Continued Examination, but before action by the USPTO does not reduce PTA.
- *Chudik v. Hirshfeld*, 987 F.3d 1033, 1035 (Fed. Cir. 2021) C-delay requires "a reversal decision made by the Board or a reviewing court, thus excluding time spent on a path pursuing such a decision when, because of an examiner reopening of prosecution, no such decision is ever issued."

9. Patent Term Extension ("PTE")

Overview

- **Eligible Patents:**
  - That claim "a product, a method of using a product, or a method of manufacturing a product"
  - Unexpired
  - Not previously extended
  - Criteria in 35 U.S.C. § 156

- **Eligible drugs: the *active ingredient* of:**
  1. New drugs, antibiotic drugs, or human biological products [§ 156(f)(2)(A)]
  2. New animal drugs or veterinary biological products not primarily made by recombinant methods [§ 156(f)(2)(B)]

  - Must be first permitted commercial marketing [§ 156(a)(5)(A)]

9. Patent Term Extension ("PTE")

- **PTE Applications:**
  - File within 60 days of product approval
  - Triggers back-and-forth between PTO and regulatory agency (FDA/USDA)
  - Agencies determine regulatory review period and PTE period
  - Third parties can file revision request or due diligence petition
  - Applicant can request reconsideration

- Maximum of **5 years** of PTE
- Cannot extend term past **14 years from approval**
- Only covers period of regulatory review that occurs after patent issuance
- PTE is the sum of:
  - All of "review phase" days, and
  - ½ of "testing phase" days, but
  - reduced by any period that application wasn't diligent during regulatory review

9. Patent Term Extension ("PTE")

***Biogen Int'l v. Banner Life Sciences*, 956 F.3d 1351 (Fed. Cir. 2020)**

- Aff'd DCT finding that ""the **scope** of a patent term extension under 35 U.S.C. § 156 only includes the **active ingredient of an approved product, or an ester or salt** of that active ingredient, and the product at issue does not fall within one of those categories."
- Branded product was Tecfidera® with active ingredient dimethyl fumarate (DMF); monomethyl fumarate (MMF).
  - DMF is effective a prodrug of MMF, because DMF metabolizes to MMF in the body. So Biogen argued that that active ingredient in DMF *is* MMF.
  - CAFC rejected that argument – held that MMF does not fall within statutory definition.
- Settled longstanding divergence in CAFC case law –
  - *Glaxo v. Quigg* (1990) held that an ester compound of an active was entitled to its own PTE extension separate from previous carboxylic acid compound; found that active ingredient as the active in the product *before* administration.
  - *Pfizer v. Dr. Reddy's* (2004) held that PTE for active (amolodipine) covered a later salt of the active (maleate); found that active ingredient is the "active moiety" regardless of the form of administration.
  - Held that neither applied; but effectively followed *Glaxo*.

10. Willfulness and Opinions

35 U.S.C. 284 Damages.

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d).

10. Willfulness and Opinions

- **What Matters When Deciding Willfulness** − *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923 (2016)
  - "The **subjective willfulness** of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless." 136 S. Ct. at 1933
  - "Awards of enhanced damages under the Patent Act over the past 180 years establish that they are not to be meted out in a typical infringement case, but are instead designed as a 'punitive' or 'vindictive' sanction for egregious infringement behavior. The sort of conduct warranting enhanced damages has been variously described in our cases as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or − indeed − characteristic of a pirate." 136 S. Ct. at 1932
    - Practice Tip: Don't act like a pirate!
- **Willfulness Requires Deliberate or Intentional Infringement** − *SRI Int'l, Inc. v. Cisco Sys.*, 14 F.4th 1323 (Fed. Cir. 2021)
  - "To eliminate confusion created by our reference to the language 'wanton, malicious, and bad-faith' in *Halo*, we clarify that it was not our intent to create a heightened requirement for willful infringement. . . . under Halo, the concept of 'wilfullness' requires a jury to find no more than deliberate or intentional infringement." 14 F.4th at 1329-30

10. Willfulness and Opinions

- **Key Aspects of the Opinion** – *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182 (Fed. Cir. 1998)
  - "As a general matter, a potential infringer with actual notice of another's patent has an affirmative duty of care that usually requires the potential infringer to obtain competent legal advice before engaging in any activity that could infringe another's patent rights." 156 F.3d at 1190
  - "an important factor in determining whether willful infringement has been shown is whether or not the infringer obtained the opinion of counsel. . . . However, the legal opinion must be 'competent' or it is of little value in showing the good faith belief of the infringer." 156 F.3d at 1191
  - "Obtaining an objective opinion letter from counsel also provides the basis for a defense against willful infringement. In order to provide such a prophylactic defense, however, counsel's opinion must be premised upon the best information known to the defendant. . . . Whenever material information is intentionally withheld, or the best information is intentionally not made available to counsel during the preparation of the opinion, the opinion can no longer serve its prophylactic purpose of negating a finding of willful infringement." 156 F.3d at 1191
    - Practice Tip: Make sure counsel has access to the best information

10. Willfulness and Opinions

- **There Should Be Reliance On The Opinion** − *Omega Patents, LLC v. CalAmp Corp.,* 920 F.3d 1337 (Fed. Cir. 2019)
  - "As to willfulness, an accused infringer's reliance on an opinion of counsel regarding noninfringement or invalidity of the asserted patent remains relevant to the infringer's state of mind post-*Halo*." 920 F.3d at 1353

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