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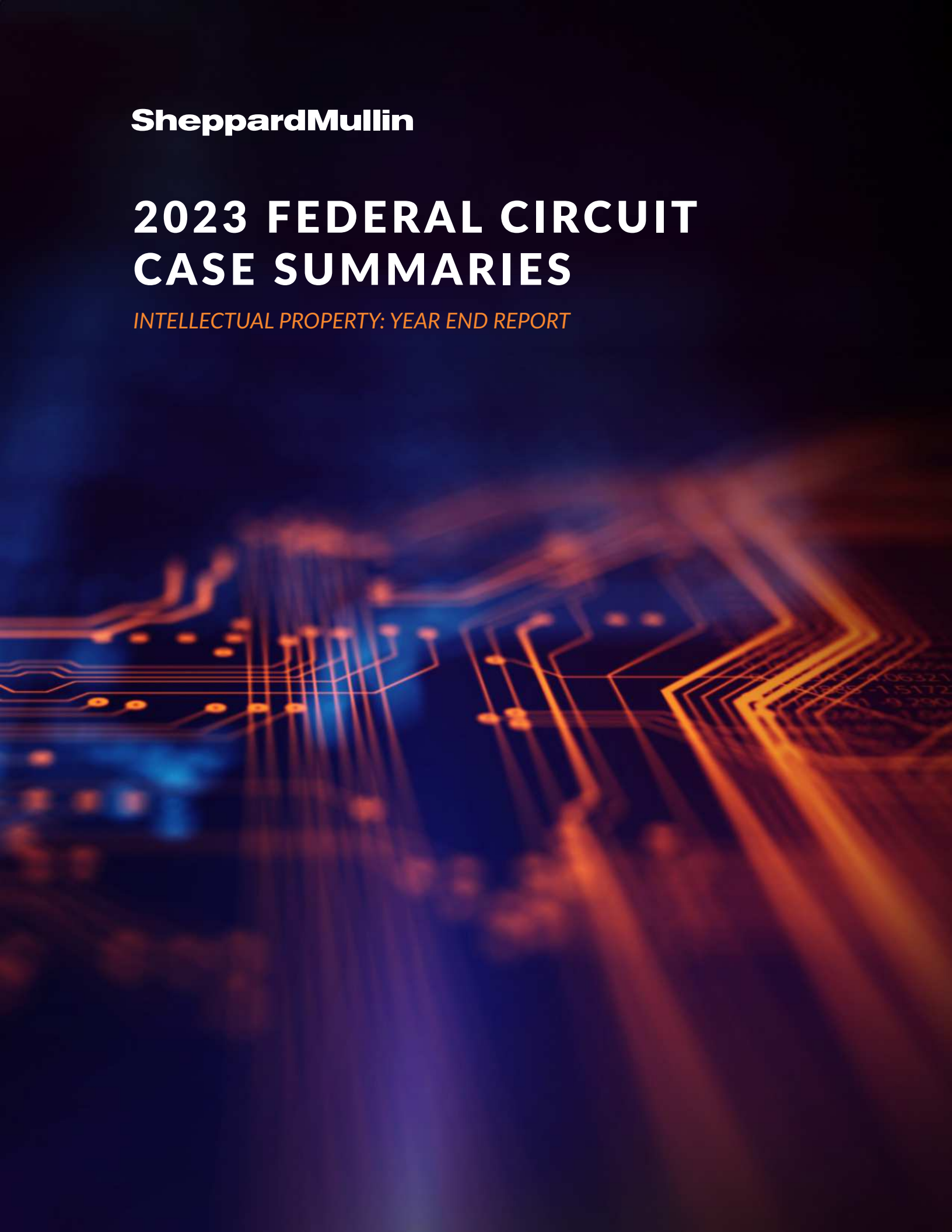
2023 FEDERAL CIRCUIT CASE SUMMARIES

INTELLECTUAL PROPERTY: YEAR END REPORT



Dear Clients and Friends,

We are pleased to share Sheppard Mullin's inaugural "Year in Review" report that collects and reports on most key patent law-related Federal Circuit decisions for 2023. This is a follow up to the quarterly report we introduced in Spring 2023, which was very well received.

In this report, we have attempted to classify and summarize every precedential opinion or order regarding patent cases issued by the Federal Circuit last year.

If you would like to receive this report directly, please email us at the address below. Or, sign up for our Intellectual Property Law Blog, which includes this information as the decisions appear (or as close as possible).

Warm regards,

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* *Most cases include summaries with the exception of a few that are not included due to our client relationships. They are included in the statistics.*

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2023 Decisions At-A-Glance

There were 75 precedential decisions in 2023, which we have broken down statistically into a few different categories.

Appeals originated from:

37 PTO

34 District Court

2 ITC

2 Writ

Results:

42 Affirmed on all issues

22 Reversed

8 Mixed Result

2 Writs of Mandamus Granted

1 Dismissed for lack of standing

Appeals originated from and the results:

PTO

23 of **37** Affirmed, **11** of **37** Reversed, **2** of **37** Mixed, and **1** Dismissed for Lack of Standing

District Court

17 of **34** Affirmed, **11** of **34** Reversed, and **6** of **34** Mixed

The most reversed issue was claim construction.

Industries:

31 Hi-Tech

22 Life Science

9 Consumer Product

7 Medical Device

3 Oil/Gas

2 Electronic Cigarette

1 Other

Primary issue addressed: **4** 101 | **5** 102 | **16** 103 | **5** 112 | **1** 315 | **14** Claim Construction | **30** Others

Chromadex, Inc., Trustees of Dartmouth College v. Elysium Health, Inc.

No. 2022-1116 (Fed. Cir. Feb. 13, 2023)
§ 101 - Alice

By: Evan Lim

Topic

This case addresses whether the district court's grant of summary judgment was proper based on the district court's finding that the asserted claims of U.S. Patent No. 8,197,807 ("the '807 patent") were invalid under 35 U.S.C. § 101 for being directed to a natural phenomenon.

Background

"The '807 patent is directed to dietary supplements containing isolated nicotinamide riboside ("NR"), a form of vitamin B3 naturally present – in non-isolated form – in cow's milk and other products." Elysium moved for summary judgment, arguing that the asserted claims were invalid under 35 U.S.C. § 101. The district court granted the motion and entered judgment of invalidity, concluding that isolated NR is a naturally occurring vitamin present in cow milk, stating that "the decision to create an oral formulation of NR after discovering that NR is orally bioavailable is simply applying a patent-ineligible law of nature." *ChromaDex, Inc. v. Elysium Health, Inc.*, 561 F. Supp. 3d 460, 467 (D. Del. 2021).

Issue(s)

- Is the act of isolating NR equivalent to how NR naturally exists in milk patent ineligible under 35 U.S.C. § 101?

Holding(s)

Court of Appeals affirms the district court's invalidity judgment.

Reasoning

The district court looks to the ruling of the Supreme Court's decision in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013) where the Supreme Court found that "Myriad did not create or alter any of the genetic information encoded in the $BRCA_1$ and $BRCA_2$ genes. The location and order of the nucleotides existed in nature before Myriad found them… Myriad did not create anything. To be sure, it found an important and useful gene, but ***separating that gene from its surrounding genetic material is not an act of invention***… Myriad's claims [are not] saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a non-naturally occurring molecule." *Myriad*, 569 U.S. at 590-593 (emphasis added). The Supreme Court ruled in *Myriad* that "a naturally occurring DNA segment is a ***product of nature and not patent eligible merely because it has been isolated***." *Id.*, 569 U.S. at 579 (emphasis added).

Appellants argued that the claimed compositions are advantageous over milk "because the isolation of NR allows for significantly more NAD+ biosynthesis than is found in milk and that the large quantity of NR itself *can alone* increase NAD+ biosynthesis." However, the Court found that the asserted claims "do not require any minimum quantity of isolated NR [nor] do these claims attribute the claimed increase in NAD+ biosynthesis to the isolated NR, requiring only that the *composition* increase NAD+ production."

Appellants further argued that the claims "possess markedly different characteristics that render them patent-eligible" in that the "'NR is found in milk in only trace amounts'" and the "'little NR [that] is found in milk is not bioavailable because it is bound to the lactalbumin whey protein." The Court concludes that regardless of there only being trace amounts of NR in milk, nonetheless "increases NAD+ biosynthesis (albeit because it contains tryptophan). Also, the Court stressed that the claims "do not require any specific quantity of isolated NR, and the district court's construction for 'isolated [NR],' which Appellants do not challenge, does not require that the NR be separated from the lactalbumin whey protein but only from '*some* of the other components associated with the source of [NR].'" "The district court construed 'isolated [NR]' to mean '[NR] that is separated or substantially free from at least some other components associated with the source of [NR].'"

The Court further stated that while "the claims cover several different composition embodiments, some of which are structurally different from milk … the claims also encompass – as both parties agree – at least one embodiment that covers milk, except that the NR element is 'isolated.' Because the claims are broad enough to encompass a product of nature, it is invalid under § 101."

Thus, the Court concluded that the "claimed compositions remain indistinguishable from natural milk because, other than separation form some other components, the isolated NR is no different structurally of functionally from its natural counterpart in milk." "Milk, like the claimed compositions, undisputedly 'increase[s] NAD+ biosynthesis' upon oral administration. The claimed compositions do not exhibit markedly different characteristics from natural milk and are, therefore, invalid for claiming a patent-ineligible product of nature."

Therefore, "the act of isolating the NR compared to how NR naturally exists in milk is not sufficient, on its own, to confer patent eligibility."

Hawk Technology Systems, LLC v. Castle Retail, LLC

No. 2022-1222 (Fed. Cir. Feb. 17, 2023)
§ 101 - Alice

By: Li Guo

Topic

This is a § 101 case, and addresses converting a 12(b)(6) motion to an MSJ under 6th Circuit law.

Background

Hawk Technology System ("Hawk") appealed the district court's decision that found the patent invalid under § 101.

The patent at issue—U.S. Pat. No. 10,499,091 (the '091 patent)—relates to a method of viewing multiple simultaneously displayed and stored video images on a remote viewing device of a video surveillance system. The Federal Circuit focused its § 101 analysis on claim 1 of the '091 patent, as reproduced below:

1. A method of viewing, on a remote viewing device of a video surveillance system, multiple simultaneously displayed and stored video images, comprising the steps of:

   - receiving video images at a personal computer based system from a plurality of video sources, wherein each of the plurality of video sources comprises a camera of the video surveillance system;
   - digitizing any of the images not already in digital form using an analog-to-digital converter;
   - displaying one or more of the digitized images in separate windows on a personal computer based display device, using a first set of temporal and spatial parameters associated with each image in each window;
   - converting one or more of the video source images into a selected video format in a particular resolution, using a second set of temporal and spatial parameters associated with each image;
   - contemporaneously storing at least a subset of the converted images in a storage device in a network environment;
   - providing a communications link to allow an external viewing device to access the storage device;

- receiving, from a remote viewing device remoted located remotely from the video surveillance system, a request to receive one or more specific streams of the video images;
- transmitting, either directly from one or more of the plurality of video sources or from the storage device over the communication link to the remote viewing device, and in the selected video format in the particular resolution, the selected video format being a progressive video format which has a frame rate of less than substantially 24 frames per second using a third set of temporal and spatial parameters associated with each image, a version or versions of one or more of the video images to the remote viewing device, wherein the communication link traverses an external broadband connection between the remote computing device and the network environment; and
- displaying only the one or more requested specific streams of the video images on the remote computing device.

In addition to the § 101 issue, Hawk also asserted that the district court erred in its decision to grant the motion to dismiss because the motion was procedurally premature under Rule 12, where the district court held a technical briefing and allegedly considered testimony and evidence such as appellee's cited references, schematic PowerPoint and appellee's CEO's statement at the technical briefing.

Issue(s)

- Is the '091 patent invalid under *Alice*?
- Did the district court err when it did not expressly reject matters outside the pleadings and failed to treat the motion as one for summary judgment under Rule 56?

Holding(s)

- Yes.
- Yes, but the error is harmless.

Reasoning

Under *Alice* step one, citing *Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC*, 874 F.3d 1329 (Fed. Cir. 2017), the Court found that the '091 patent claims are directed to a method of receiving, displaying, converting, storing, and transmitting digital video "using result-based functional language." Further citing *Adaptive Streaming Inc. v. Netflix, Inc.*, 836 F. App'x 900 (Fed. Cir. 2020), the Court found that the claims are directed to those same general abstract ideas—displaying images, converting them into a format, transmitting them, and so on. Under *Alice* step two, the Court found the claims only use generic functional language to achieve the purported solution and require nothing other than conventional computer and network components operating according to their ordinary functions. Nor did the Court see anything inventive in the ordered combination of the claim limitations. In sum, the Court held that the '091 patent is patent ineligible because its claims are directed to an abstract idea and fail to transform that abstract idea into patent-eligible subject matter.

Because this is a procedural issue not unique to patent law, the Court looks to the law of the applicable regional circuit—the Sixth Circuit. Under Rule 12(d), if matters outside the pleadings are presented to, and not excluded by, the court, the motion must be treated as one for summary judgment under Rule 56. Under Sixth Circuit law, a motion to dismiss must ordinarily be decided without resort to matters outside the pleadings; a district court's failure to expressly reject evidence attached to the briefs triggers its duty to treat the motion as one for summary judgment.

Here, the Court found that the district court erred when it did not expressly reject the outside matters or treat the motion as one for summary judgment under Rule 56. But the Court held that the district court's error was harmless because, first, the district court did not discuss these outside materials in its decision. Secondly, the Court noted that the district court holding a technical briefing is simply a procedural fact and where a district court holds a technical briefing, e.g., a technical tutorial, and no matters outside the pleading are presented, it need not convert the motion to one for summary judgment under Rule 56. Finally, the Court noted that the district court expressly stated that it was ruling under 12(b)(6), and its analysis was based wholly on the legal sufficiency, *vel non*, of the plaintiff's claim, and the dismissal can be justified without reference to any extraneous matters.

Sanderling Management v. Snap Inc.

No. 2021-2173 (Fed. Cir. Apr. 12, 2023)
Alice – 35 U.S.C. § 101

By: Fred Chung

Topic

This case addresses patent eligibility under *Alice* and whether the district court should have afforded the patent owner leave to amend its complaint.

Background

Sanderling asserted three patents sharing a common specification against Snap in the Northern District of Illinois. The claims are directed to a method of determining a user's location with GPS and displaying images the user based on their location. Snap moved to transfer venues and to dismiss, asserting the patents were invalid for being directed to a patent-ineligible abstract idea under *Alice*. Sanderling opposed Snap's motions.

Before deciding Snap's motion to dismiss, the Northern District of Illinois court granted Snap's motion to transfer the case to the Central District of California. The Central District of California court then granted Snap's motion to dismiss with prejudice and denied Sanderling's request for leave to amend its complaint, which Sanderling did not make until the hearing. The district court further denied Sanderling's motion for reconsideration.

Issue(s)

- Whether the district court oversimplified the claims under step one of the *Alice* tests.
- Whether the district court erred by not construing claim terms.
- Whether Sanderling's alleged factual disputes precluded ruling on the motion to dismiss.
- Whether the district court deprived the patents of their statutory presumption of validity and improperly put the burden of proof on the patentee by deciding contrary to the prosecution history where the PTO had determined the presence of an inventive concept.
- Whether Sanderling's proposed amendments to its complaint were futile.

Holding(s)

- The district court's formulation of the abstract idea ("'of providing information – in this case, a processing function – based on meeting a condition,' e.g., matching a GPS location indication with a geographic location.") was correct.
- When proposed constructions have not been provided, the court need not engage in claim construction before resolving a § 101 motion, if the claims are directed to ineligible (or eligible) subject matter under all plausible constructions.
- A patentee's conclusory and generalized allegations of factual disputes do not support denial of a motion to dismiss.
- Improving scalability and speed does not provide innovative concept to an abstract idea.
- Denial of reconsideration was proper because the proposed amendment to the complaint was futile.

Trinity Info Media, LLC, fka Trinity Intel Media, LLC, v. Covalent, Inc.

No. 2022-1308 (Fed. Cir. July 14, 2023)

By: Evan Lim

Topic

This case addresses whether patents relating to methods and systems for connecting users based on their answers to polling questions claim patentable subject matter under 35 U.S.C. § 101.

Background

Trinity sued Covalent for patent infringement of U.S. Patent 9,087,321 ("the '321 patent") and U.S. Patent 10,936,685 ("the '685 patent") (collectively, "the challenged patents"). The challenged patents are related and both trace their priority date to U.S. Provisional Application No. 61/309,038, filed on March 1, 2010. The challenged patents both teach a similar claimed invention that is "directed to a poll-based networking system that connects users based on similarities as determined through poll answering and provides real-time results to the users." '321 patent col. 1 ll. 53-56. The '685 patent contains additional disclosures discussing progressive polling for ecommerce systems. '685 patent col. 2 l. 1 to col. 3 l. 60.

Trinity asserted claims 1-3, 8 and 20 of the '321 patent and claims 2, 3, 12-14, 16, 17, 20-22, 24 and 25 of the '685 patent. Covalent filed a motion to dismiss asserting the claims are invalid under 35 U.S.C. § 101. The District Court granted Covalent's motion to dismiss, finding the asserted claims were directed to the abstract idea of "matching users who gave corresponding answers to a question" and did not contain an inventive concept. The District Court further described claim 1 of the '321 patent as not improving computer functionality but instead using "generic computer components as tools to perform the functions faster than a human would."

Issue(s)

- Whether the challenged patents are directed to an abstract idea and do not include an inventive concept that is an improvement over the general functionality of a computer.

Reasoning

The claims are directed to the use of computers as a tool; here, a tool to identify when a condition is met and then to distribute information based on satisfaction of that condition. The challenged claims here are distinguishable from *McRO v. Bandai* because they claim a much more generic set of steps than McRO's specific claim language. Here, the claims have a "distribution rule" that merely receives, matches, and then distributes the corresponding function based on the user's location.

Sanderling identified terms for claim construction, but failed to provide constructions. To determine whether claim construction is required to resolve a motion to dismiss, the patentee should propose specific constructions and articulate how adoption of the constructions would materially impact the analysis at step one (and/or at step two). Sanderling failed to do so.

A district court has the discretion to require an opposing party to identify, and articulate the significance of, specific factual disputes that purportedly make granting the motion improper. Sanderling failed to timely identify any specific factual disputes.

"No amendment to a complaint can alter what a patent itself states." Thus, the proposed amendments to add conclusory statements that steps were not well-known, routine, and conventional to the complaint were futile. District courts need not credit conclusory allegations. Courts are not required to defer to the Patent Office determinations as to eligibility, because review under ¶ 101 is de novo.

Holding(s)

The Federal Circuit affirmed the District Court's finding that the challenged patents are patent ineligible under § 101.

Reasoning

Section 101 of the Patent Act defines patent-eligible subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. The Supreme Court has long held that there is an "implicit exception" in § 101 in that "[l]aws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (quoting *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013)).

To determine if claims contain patent-eligible subject matter, the two-step framework set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 77–80 (2012) is applied. Step one, "determine whether the claims at issue are directed to one of those patent-ineligible concepts," such as an abstract idea. *Alice*, 573 U.S. at 217. Step two, "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 patent-eligible application." *Alice*, 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 78–79). Essentially, step two is described as a search for an "inventive concept" – an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon ineligible subject matter.

When analyzing claims under § 101 for a motion to dismiss, courts may make a determination before conducting claim construction and fact discovery. To invoke a need for claim construction or discovery before an analysis of asserted claims can be made, the patentee must propose a specific claim construction or identify specific facts that need development and explain why those circumstances must be resolved before the scope of the claims can be understood for § 101 purposes. It is not enough to invoke a generic need for claim construction or discovery to avoid a grant of a motion to dismiss under § 101.

Alice/Mayo Step 1

To determine if a claim is directed to a patent-ineligible concept, such as an abstract idea, "the focus of the claimed advance over the prior art [is evaluated] to determine if the claim's character as a whole is directed to excluded subject matter." *PersonalWeb Techs. LLC v. Google LLC*, 8 F.4th 1310, 1315 (Fed. Cir. 2021) (quoting *Intell. Ventures I LLC v. Erie Indem. Co.*, 850 F.3d 1315, 1325 (Fed. Cir. 2017)). "[W]hile the specification may help illuminate the true focus of a claim, when analyzing patent eligibility, reliance on the specification must always yield to the claim language in identifying that focus." *Charge-Point, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 766 (Fed. Cir. 2019). In the context of software-based inventions, *Alice/Mayo* step one "often turns on whether the claims focus on the specific asserted improvement in computer capabilities or, instead, on a process that qualifies as an abstract idea for which computers are invoked merely as a tool." *In re Killian*, 45 F.4th 1373, 1382 (Fed. Cir. 2022) (quoting *Finjan, Inc. v. Blue Coat Sys., Inc.*, 879 F.3d 1299, 1303 (Fed. Cir. 2018)).

The Federal Court determined that the independent claims of the challenged patents are focused on collecting information, analyzing it, and displaying certain results, which places them in a class of claims directed to a patent-ineligible concept, as a human mind could review people's answers to questions and identify matches based on those answers. While the independent claims may state that such operations be performed in a particular environment, such as on a hand-held device, a web server, a database or a match aggregator, such requirements or limitations to an abstract idea do not change the focus the claims. Additionally, including specificity to the operations as found in the dependent claims, such as performing matches based on gender, varying the number of questions asked, and/or displaying other users' answers, also do not change the focus of the claims as they merely add trivial variations of the abstract idea.

Although humans could not mentally perform "nanosecond comparisons" and aggregate "result values with huge numbers of polls and members," as argued by Trinity, the claims do not require such operations. Moreover, even though a human could not perform operations of claims as quickly as a computer using generic computer components, such claims have been found to be directed to an abstract idea. *See Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350, 1351, 1353–54 (Claims were found to be directed to an abstract idea even though a human

could not "detect[] events on an interconnected electric power grid in real time over a wide area and automatically analyz[e] the events on the interconnected electric power grid.") *See Charge-Point*, 920 F.3d at 766–67 (Although a human cannot communicate over a computer network without the use of a computer, claims directed to enabling "communication over a network" were held to be focused on an abstract idea.)

The Federal Circuit further found that the challenged patents' specifications confirm that the asserted claims are directed to an abstract idea that merely seeks to use computers as a tool, not on an improvement in computer capabilities. The specifications of the challenged patents frame the inventor's problem in terms of how to improve existing polling systems by performing progressive polling and focuses on details of receiving and comparing answers to generate matches, and not on how to improve computer technology. The challenged patents also repeatedly note in the specifications that the invention is not limited to specific technological solutions, including, for example, disclosing that the invention may be practiced without necessarily being limited to the specific details described, that there are numerous techniques for determining a likelihood of a match, and that physical connections, protocols and communication procedures of the Internet are well known to those of skill in the art, confirming that the problem being solved by the invention is the ability to perform the abstract idea of matching based on questioning, and not an improvement to computer technology. Thus, any use of specific components, such as a unique identification, match servers, and a match aggregator, merely place the abstract idea in the context of a distributed networking system and does not change the focus of the asserted claims from an abstract idea, as described in the specification.

Alice/Mayo Step 2

Where a claim is directed to an abstract idea under step 1, it is to be determined whether the claim includes "an inventive concept sufficient to transform the claimed abstract idea into a patent-eligible application" and "amounts to significantly more than a patent upon the [ineligible concept] itself," rather than simply stating the abstract idea while adding the words "apply it." *Alice*, 573 U.S. at 217-218, 221. A determination of whether a claim has an "inventive concept" would include an examination of the additional elements of the claim, both individually and as an ordered combination, to determine if such additional elements "transform the nature of the claim" into a patent-eligible application. *Mayo*, 566 U.S. at 78, 79. Trinity asserts arguments that the asserted claims contain inventive concepts because the prior art did not include, alone or in combination, certain features disclosed in the asserted claims, including match servers, a match aggregator, a mobile device and a mobile application.

Trinity further asserts that because these features are not disclosed in the prior art, the present invention "includes an advance over the prior art and an improvement over a general-purpose computer." The Federal Circuit has found that conclusory allegations that the prior art lacks elements of asserted claims, and that such elements are an advance over the prior art and an improvement over a general-purpose computer, are insufficient to demonstrate an inventive concept. *See Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 716 (Fed. Cir. 2014) ("That some of the eleven steps were not previously employed in this art is not enough—standing alone—to confer patent eligibility upon the claims at issue."); *see also Customedia Techs., LLC v. Dish Network Corp.*, 951 F.3d 1359, 1364 (Fed. Cir. 2020) ("[C]laiming the improved speed or efficiency inherent with applying the abstract idea on a computer [is] insufficient to render the claims patent eligible as an improvement to computer functionality." (citation omitted), *see also OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1363 (Fed. Cir. 2015) ("[R]elying on a computer to perform routine tasks more quickly or more accurately is insufficient to render a claim patent eligible.").

The Federal Circuit concluded that the asserted claims use general-purpose processors to perform the steps of collecting, transmitting, receiving, and compiling users' answers and matches. The Federal Circuit found "invocations of computers and networks that are not even arguably inventive are insufficient to pass the test of an inventive concept in the application of an abstract idea." *SAP Am. Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1170 (Fed. Cir. 2018) (quoting *Elec. Power*, 830 F.3d at 1355). As such, use of databases and multiple processors do not add an inventive concept where the claims merely require "already available computers, with their already available basic functions, to use as tools in executing the claimed process." *SAP Am.*, 898 F.3d at 1169-70. Further, when looking at the additional elements of the claim in an ordered combination, the Federal Circuit found that the asserted claims are organized in an expected way – receiving user information, asking the user questions, receiving answers from the user, identifying and displaying a match based on the answers – thus concluding that no inventive concept is displayed. Thus, the asserted claims of the patents do not provide an inventive concept by virtue of their use of certain features and components, such as multiple processors, match servers, unique identifications, and/or a match aggregator.

§ 102 - Public Use

Minerva Surgical, Inc. v. Hologic, Inc.

No. 2021-2246 (Fed. Cir. Feb. 15, 2023)
§ 102 – Public Use

By: Fred Chung

Topic

This case examined the requirements ("in public use" and "ready for patenting") of the public use bar to patentability under pre-AIA 35 U.S.C. § 102(b).

Background

After being sued by Minerva for infringement of U.S. Patent No. 9,186,208 ("the '208 patent"), Hologic moved for summary judgement of invalidity in district court under the public use bar (§ 102(b)). Based on information uncovered during discovery, Hologic alleged that Minerva brought a device called "Aurora" to the 38th Global Congress of Minimally Invasive Gynecology in Nov. 20, 2009, more than a year before the '208 patent's Nov. 7, 2011 priority date, and that Aurora disclosed all limitations of the asserted claims. Minerva argued that the limitation of "the inner and outer elements have substantially dissimilar material properties" ("SDMP term") was not disclosed by the Aurora product. The motion was granted on the discovery record, which showed Minerva had developed prototypes by mid-2009 and was testing these devices on extirpated human uteri, contemporaneous lab notes showing the disputed claim term, various materials touting the benefits that would stem from the disputed claim term, and further evidence of using different materials for the inner and outer elements of the Aurora device at the time. Minerva appealed.

Issue(s)

- Whether "merely display[ing]" at a public event constitutes "in public use."
- Whether the Aurora device disclosed the SDMP term.
- Whether the invention was not "ready for patenting" when Minerva was still improving the technology, which did not function for its intended purpose on "live human" uteri, at the time of disclosure.

Holding(s)

- The nature of public access granted at the event constituted public use because the display was under no limitation, restriction, or obligation of confidentiality.
- Public use may occur if the inventor used the device such that at least one member of the public without any secrecy obligations understood the invention.
- There is no genuine factual dispute as to whether the Aurora device shown at the conference disclosed the SDMP term.
- The Aurora device satisfied ready for patenting under two tests: first, because it had been reduced to practice, and second, because Minerva was in possession of enabling documentation describing the invention.

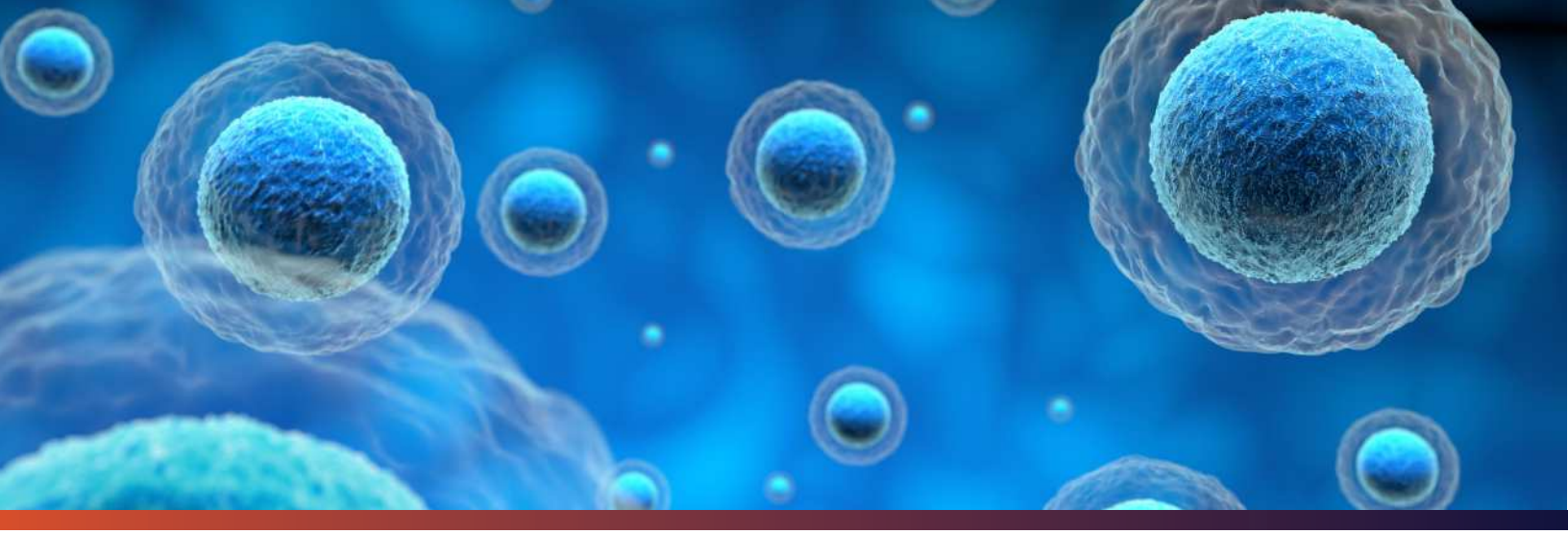
Reasoning

The record showed that Minerva brought "15 full[y] functional" Aurora devices to the AAGL2009, which was considered the "Super Bowl" of the industry. Over several days, the devices were exhibited with demonstrations to various sophisticated industry members, who were allowed to scrutinize the Aurora device closely and see how it operated. Unlike *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376 (Fed. Cir. 2007), where only a visual view of the keyboard design was provided without any disclosure of the claimed technology, here, Minerva received detailed feedback from knowledgeable individuals, indicating sufficient disclosure to recognize and understand the SDMP technology. No confidentiality obligations were imposed on attendees to the conference.

Minerva's documentation about the Aurora device from before, and shortly after, the event expressly discloses that the device has the SDMP term or touts benefits that are derived from the device having the SDMP technology. Minerva brought fully functional devices to the conference, and the feedback received described features Minerva attributes to the SDMP term. Furthermore, the inventor admitted that the disclosed device "[l]ikely" embodied the SDMP term when confronted with evidence.

Minerva reduced the invention to practice by creating working prototypes that embodied claim 13 and worked for the intended purpose of performing endometrial ablation. Case law does not require imposing a "live human" requirement where nothing in the intrinsic record points to such limitation. Minerva's further improvements amounts to mere "later refinements" or "fine tuning." Even applying the heightened standard, the evidence suggests a reduction to practice (studies concluding acceptability for clinical use, inventor testimony of being nearly "perfect").

The invention was also ready for patenting, due to the detailed drawings and detailed descriptions in the 2009 lab notebook which included CAD drawings.



Arbutus Biopharma Corporation v. Modernatx, Inc.

No. 2020-1183 (Fed. Cir. April 11, 2023)

By: Evan Lim

Topic

This case addresses the legal standard for inherent anticipation.

Background

The '127 patent is directed to an invention that provides stable nucleic acid-lipid particles ("SNALP") that have non-lamellar structure and "comprise a nucleic acid … methods of making SNALP, and methods of delivering and/or administering the SNALP." '127 patent, Abstract. The '127 patent states that its purpose is to allow for more efficient methods and compositions for introducing nucleic acids into cells and methods of downregulating gene expression. '127 patent, col. 2 ll. 54-61. The '127 patent identifies five formulations of various compositions that can be prepared by either Stepwise Dilution Method ("SDM") or Direct Dilution Method ("DDM"). '127 patent, Tables 1, 3; col. 104 ll. 44-60; col. 105 ll. 53-64.

Modernatx filed a petition for *inter partes* review ("IPR") challenging claims 1-22 of the '127 patent for being anticipated by U.S. Patent No. 8,058,069 (the "'069 patent"). The Board instituted the IPR and issued a final written decision ("FWD") finding all 22 claims of the '127 patent anticipated by the '069 patent.

Issue(s)

- Whether claim 1(d) of the '127 patent is inherently anticipated by the '069 patent.

Holding(s)

The Federal Circuit affirmed the Board's analysis that the '127 patent is inherently anticipated by the '069 patent.

Reasoning

The main issue before the Board was whether claim 1(d) of the '127 patent – wherein at least about 95% of the particles in the plurality of particles have a non-lamellar morphology (the "Morphology Limitation") – is inherently disclosed in the '069 patent. Modernatx argued that the Morphology Limitation, while not expressly mentioned in the prior art, is an "inherent natural property" resulting from the lipid composition of the formulation and formation process. *Decision* at *11. Although Arbutus (1) argued that there was no presumption of inherency, (2) argued that there was no evidence (such as testing or reasoning) showing that the '069 patent and its formulations would necessarily have the same morphology as disclosed by the '127 patent and (3) submitted experimental evidence from an expert to demonstrate that the Morphology Limitation was not met by formulations from the '069 patent, the Board found Arbutus's arguments and evidence submission unavailing.

The Federal Circuit states a limitation is inherent if it is the "natural result flowing from" the prior art's explicit disclosure. *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). A patent "can be invalid based on inherency when the patent itself makes clear that a limitation is 'not an additional requirement imposed by the claims... but rather a property necessarily present'." *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 946 F.3d 1322, 1332 (Fed. Cir. 2020) (quoting *In re Kubin*, 561 F.3d 1351, 1357 (Fed. Cir. 2009)). Thus, inherent anticipation requires "merely that the disclosure of the prior art is sufficient to show that the natural result flowing from the operation as taught in the prior art would result in the claimed product." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343–44 (Fed. Cir. 2005) (internal quotation marks omitted) (modifications in the original).

The Federal Circuit further explained that "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." *Bristol–Myers Squibb Co. v. Ben Venue Labs, Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001). Also, "[i]nsufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation." *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1349 (Fed. Cir. 1999).

The Federal Circuit also discussed the effect of incorporated references. When a reference or material from various documents is incorporated, they are "effectively part of the host document as if [they] were explicitly contained therein." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). While looking at the reference as a whole, the court will "conclude whether or not that reference discloses all elements of the claimed invention arranged as in the claim." *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 n.5 (Fed. Cir. 2008).

The Federal Circuit first found that there is substantial evidence supporting the Board's finding that the formulations in the '069 patent and the '127 patent "are the same or essentially the same." Second, the Federal Circuit found that there is substantial evidence supporting the Board's finding that the '069 patent and the '127 patent disclose and describe DDM the same way by referring to the '031 publication and "the Direct Dilution Method" to provide details for carrying out the direct dilution process. Third, the Federal Circuit found there was substantial evidence to support the Board's finding of inherent anticipation in that making the disclosed formulations according to the disclosed process, which are similarly disclosed in both the '069 and '127 patents with the disclosures of the incorporated references, would "naturally result in a composition having the claimed morphological property." *Decision* at *21.

Therefore, the Federal Circuit held that there was substantial evidence supporting the Board's finding that independent claim 1 and its morphological property are inherently anticipated by the disclosures of the '069 patent and its incorporated references.

Medtronic, Inc., Medtronic Vascular, Inc. v. Teleflex Innovations S.A.R.L.

No. 2021-2356 (Fed. Cir. May 24, 2023)

By: Evan Lim

Topic

This case addresses whether the final written decisions in a consolidated *inter partes* appeal ("IPR") correctly found that U.S. Patent 7,736,355 ("the '355 patent") does not qualify as prior art to related U.S. Patents 8,048,032, RE45,380, RE45,776, RE45,760, and RE47,379 (collectively, "the challenged patents") under pre-AIA's first-to-invent provisions.

Background

The challenged patents all claim priority to a common application filed on May 3, 2006, and share a common specification. The challenged patents are directed to guided-extension catheters that use a tapered inner catheter that runs over a standard coronary guidewire to reduce the likelihood that a guide catheter will dislodge from the coronary artery's opening.

Teleflex, owner of the challenged patents that were developed by Vascular Solutions Inc. ("VSI"), asserted that the claimed invention of the challenged patents was conceived in early 2005. Medtronics filed five IPR petitions using the '355 patent as the primary prior art reference under pre-AIA 35 U.S.C. § 102(e). Teleflex filed its responses and evidence addressing conception and reduction to practice, and argued that the '355 patent does not qualify as prior art because the claimed inventions (1) were conceived prior to the filing date of the '355 patent, and (2) were (a) actually reduced to practice before the filing date of the '355 patent or (b) diligently pursued until their constructive reduction to practice through their effective filing in May 2006.

The U.S. Patent and Trademark Office Patent Trial and Appeal Board (the "Board") found that the evidence demonstrated that the claimed inventions were (1) conceived no later than August 2005, and (2) either (a) actually reduced to practice for their intended purpose in April and July 2005, or (b) diligently worked on toward constructive reduction to practice through May 3, 2006, thus finding that the '355 patent does not qualify as prior art to the challenged patents under pre-AIA 35 U.S.C. § 102(e). The Board concluded that Medtronic failed to demonstrate that the challenged claims were unpatentable.

Issue(s)

- Whether the Board correctly found that the '355 patent failed to qualify as prior art to the challenged patents under pre-AIA's first-to-invent provisions.

Holding(s)

The Federal Circuit affirmed the Board's final written decisions finding that the '355 patent failed to qualify as prior art to the challenged patents, thus finding the challenged claims were not proven to be unpatentable.

Reasoning

To establish actual reduction to practice before the filing date of the '355 patent, it must be shown that "(1) [the inventors] constructed an embodiment or performed a process that met all the limitations of the [claimed invention]; and (2) [the inventors] determined that the invention would work for its intended purpose." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998).

Medtronic argued that the Board erred in identifying the intended purpose of the claimed invention. While Medtronic argued that the Board should not have relied on extrinsic evidence to determine the intended purpose, and instead should rely on the patent's specification and claims, the Court found that while patents themselves are the most important and persuasive evidence of a patent's intended purpose, it is appropriate to consider extrinsic evidence, particularly when it does not contradict the patent itself. The Court agreed with the Board, and found that the intrinsic evidence, supported by extrinsic evidence, described the purpose of the claimed inventions to "relate to methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta" and rejected Medtronic's overly narrow proposed intended purpose.

Medtronic argued that, even if the Board's finding of the intended purpose was correct, the Board erred in not requiring comparative testing to demonstrate that the invention worked for that purpose. While Medtronic argued that Teleflex cannot prove any testing was performed, much less testing to confirm intended purpose, the Court found that "the Board thoroughly reviewed and analyzed the evidence

of testing in the records" and "the testing performed [was] sufficient to show that the claimed invention worked for its intended purpose." Specifically, the Court found that the Board accurately determined that the tests "enabled the inventors to observe the forces exerted on the prototype and the durability of the prototype," which were "sufficient to enable the inventors to confirm that the prototype would work for its intended purpose – providing increased backup support as compared with a guide catheter alone."

Medtronic additionally argued that the Board erred in relying solely on uncorroborated inventor testimony as evidence of actual reduction to practice. Inventor testimony may serve as evidence of reduction to practice, but it must be corroborated by independent evidence. *Cooper*, 154 F.3d at 1330. The Court found that "the inventor's testimony of actual reduction to practice, including that the invention worked for its intended purpose, sufficiently corroborated" since the testimony of the inventors were "supported by both documentary evidence and non-inventor testimony." Non-inventor testimony included testimony from a former Research & Development Technician at VSI, who testified that "he was both personally involved in some of the testing, and recalls watching the inventors perform testing on the prototype on multiple occasions." Documentary evidence included reports and invoices showing that "VSI ordered specialized 'hypotubes' for prototypes of the rapid exchange GuideLiner in the first half of 2005," which the Board found that the "dimensions of that hypotubing are consistent with the dimensions provided in the patents themselves and engineering drawings specific to the rapid exchange GuideLiner." While the Court agreed with Medtronic that some of the evidence in the record is unclear as to whether or not it relates to the over-the-wire GuideLiner or the rapid exchange GuideLiner, the Court found that when viewing the pertinent evidence in its entirety, the inventor's story was corroborated.

The Court found the Board's determination of actual reduction prior to the filing date of the challenged patents supported by substantial evidence affirmed the Board's finding and ruling that the '355 patent does not qualify as prior art to the challenged patents under pre-AIA 35 U.S.C. § 102(e).

Parus Holdings, Inc. v. Google LLC

Nos. 2022-1269, 2022-1270 (Fed. Cir. Jun. 12, 2023)

By: Zijian Han

Topic

This case concerns determining the prior art status of certain references in an *inter partes* review. The Federal Circuit considered whether the Patent Trial and Appeal Board (the "Board") was correct in declining to consider the patent owner's certain evidence not submitted in compliance with the Board's rules and in making a determination regarding written description requirements.

Background

Google, Samsung, and LG petitioned for *inter partes* review of two patents owned by Parus, both patents directed to an interactive voice system that allows a user to request information from a voice web browser. The parties disputed whether Kovatch, a reference identified by petitioners, qualified as prior art. In support of the position that Kovatch qualified as prior art, Parus submitted approximately 40 exhibits totaling 1,300 pages, in addition to claim charts exceeding 100 pages. However, Parus only minimally cited small portions of the material in its briefs without meaningful explanation. The Board found that Parus improperly incorporated these arguments by reference and declined to consider them.

The parties also disputed whether the publication of the application from which the challenged patents claim priority, Kurganov-262, which shares a specification with the challenged patents, was prior art. The Board found so since the common specification failed to provide written description support for certain challenged claims. Parus appealed on both issues.

Issue(s)

- Did the Board err in not considering Parus's arguments and evidence regarding antedating, which were incorporated by reference into the response and sur-reply?
- Did the Board's determinations regarding the written description requirement of 35 U.S.C. § 112 exceed its statutory authority under 35 U.S.C. § 311(b)?

Holding(s)

- No. The Board did not err in declining to consider Parus's arguments and evidence regarding antedating, which were incorporated by reference into the response and sur-reply.
- No. The Board's determinations regarding the written description requirement of 35 U.S.C. § 112 did not exceed its statutory authority under 35 U.S.C. § 311(b).

Reasoning

On appeal, Parus did not dispute that it incorporated arguments by reference and therefore violated 37 C.F.R. § 42.6(a)(3). But Parus argued that the Board erred in refusing to consider *evidence* of antedating and that the statute requires specific and persuasive attorney arguments only from the petitioner, not the patent owner. The Federal Circuit, however, found that the burden of production, which Parus assumed by attempting to antedate an asserted prior art reference, "cannot be met simply by throwing mountains of evidence at the Board without explanation or identification of relevant portions." The Federal Circuit held that meeting the burden requires some combination of "citing the relevant record evidence with specificity and explaining the significance of the produced material in briefs." It explained that the policy reasons behind the requirements include minimizing the chance that an argument may be overlooked, eliminating abuses, and preventing evisceration of page limit requirements. The Federal Circuit further held that the Board has the power to strike or to not consider submissions that do not comply with the Board's orders and rules.

Parus argued that 35 U.S.C. § 311(b) limits the scope of IPRs to the cancellation of claims based "only on a ground that could be raised under section 102 or 103." However, the Federal Circuit, relying on its precedent, held that § 311(b) "merely dictates the grounds on which an IPR petition may be based, not the issues that the Board may consider to resolve those grounds." Because Parus asserted that Kurnagov-262 is not prior art by claiming priority from the application from which it stems, the Board needed to determine whether the challenged claims satisfied the written description requirement. The Board therefore did not exceed its statutory authority.

Medtronic, Inc. v. Teleflex Life Sciences Limited

Nos. 2022-1721, 2022-1722 (Fed. Cir. Nov. 16, 2023)

By: Sofya Asatryan

Topic

The Federal Circuit considered whether U.S. Patent RE46,116 ("the '116 patent") was entitled to an alleged priority date sufficient to moot Medtronic's asserted pre-AIA §102(e) prior art reference, which depended on whether Medtronic had waived its challenged to Teleflex's asserted priority date by attempting to incorporate those arguments by reference in its *inter partes* review ("IPR") petitions, and whether the USPTO Patent Trial and Appeal Board ("PTAB") correctly found that Teleflex sufficiently demonstrated not only the date of conception, but also that the inventors had diligently reduced the claimed invention to practice.

Background

Medtronic filed two IPR petitions challenging certain claims in Teleflex's '116 patent. In the IPRs, Medtronic asserted that the "Itou" reference qualified as prior art under the pre-AIA § 102(e). Teleflex claimed that Itou was not prior art because the invention claimed in the '116 patent was conceived before Itou's critical date and was either actually reduced to practice before the critical date or diligently pursued until its constructive reduction to practice. The Board agreed with Teleflex that Itou did not qualify as prior art because "(1) the claimed invention was conceived before the critical date of Itou, (2) the claimed invention was actually reduced to practice before the critical date of Itou, and (3) the patent owner diligently pursued work on the invention until its constructive reduction to practice through its effective filing in May 2006." Medtronic appealed.

Under pre-AIA 25 U.S.C. § 102(e), patent owner may antedate an asserted prior art patent by showing conception of the claimed invention prior to the critical date *and either* actual reduction to practice prior to the reference's critical date *or* "reasonably continuous diligence" in reducing the invention to practice until its effective filing date. Here, Medtronic did not contest that the claimed invention was conceived before Itou's filing date but argued that (1) in vivo testing was required for actual reduction to practice, and (2) patentee did not exercise reasonably continuous diligence until constructive reduction to practice. Medtronic asked the Federal Circuit to reach this issue by considering the arguments it made in a separate appeal.

Issue(s)

- Whether or not *in vivo* testing was required for actual reduction to practice, and
- Whether or not the patentee exercised reasonably continuous diligence until constructive reduction to practice.

Holding(s)

The Federal Circuit held that Medtronic had waived any challenge regarding the diligence issue by attempting to improperly incorporate its arguments by referring to the Board's judgment in a separate, related IPR, but choosing not to include arguments on diligence in its opening brief. The panel rejected Medtronic's incorporation-by-reference bid, stating that trying to "incorporate by reference twenty pages from another brief in another case, amounting to over 4,000 extra words" was "a clear violation of both the motion's panel's order [denying Medtronic's motion for leave to expand its brief to 20,000 words] and our rules".

Reasoning

Since Medtronic did not include arguments in its IPR petition contesting that the claimed invention was conceived before Itou's filing date and challenge to constructive reduction to practice was deemed waived, the Federal Circuit affirmed the PTAB's decision that Itou did not qualify as prior art. Since either actual or constructive reduction to practice was sufficient to uphold the PTAB's decision, the Federal Circuit refused to decide whether *in vivo* testing was required for actual reduction to practice.

Intel Corp. v. PACT XPP Schweiz AG

No. 2022-1037 (Fed. Cir. Mar. 13, 2023)
§ 103 – Obviousness

By: Roy Jung

Topic

This case addresses evidence required to show motivation to combine.

Background

This is an appeal of the Board's Final Written Decision. The Board (i) *sua sponte* found the prior art references do not disclose a certain claim element, and (ii) that the petitioner failed to show motivation to combine two prior art references.

Standard of Review

"What the prior art discloses and whether a [POSITA] would have been motivated to combine prior art references are both fact questions" and reviewed for substantial evidence.

Issue(s)

- Whether the Board's interpretation that the prior art references do not disclose a certain claim element lacks substantial evidence.
- Whether the Board's rejection of Intel's "known-technique" rationale for a motivation to combine lacks substantial evidence.

Holding(s)

- The Board's interpretation lacks substantial evidence.
- The Board's rejection of Intel's "known-technique" rationale for a motivation to combine lacks substantial evidence "even absent any hint of suggestion in the references themselves."

Reasoning

The Board ignored Intel's proffered construction and argument that a prior art reference (i.e., Bauman) teaches the claim element-at-issue. The Federal Circuit found Bauman teaches, if not plainly discloses, the claim element-at-issue.

The Board's rejection of Intel's "known-technique" rationale for a motivation to combine lacks substantial evidence "even absent any hint of [motivation to combine] in the references themselves" because Intel showed:

- An existence of a "well-known problem";
- That a prior art reference discloses how to improve the "well-known problem"; and
- Combining the teachings of prior art references was not beyond the skill of a POSITA.

Roku, Inc. v. Universal Electronics, Inc.

No. 2022-1058 (Fed. Cir. Mar. 31, 2023)
§ 103 – Obviousness

By: Samantha Young

Topic

This case addresses the factual understanding of a person of ordinary skill in the art ("POSITA") in the context of remote control command codes formatted for transmission via two different communication methods.

Background

U.S. Patent No. 9,716,853 ("the '853 Patent") is directed to a universal control engine facilitating communication between a controlling device (*i.e.*, a remote) and an intended target appliance, e.g., TVs, sound systems, etc. Roku filed a petition for *inter partes* review based on U.S. Patent Pub. No. 2012/0249890 to Chardon ("Chardon") and other secondary references challenging that '853 Patent. Chardon is also directed to a remote control system. In particular, Chardon describes a linked database including at least two different sets of command codes—specifically, a set of Consumer Electronic Control (CEC) command codes and a set of infrared (IR) command codes that alternates use of the CEC and IR command codes depending on the configuration of the target device.

The dispute turns on whether Chardon disclosed or taught the limitation that recites: "using an identity associated with the intended target appliance to create a *listing comprised of at least a first communication method and a second communication method different than the first communication method* for use in controlling each of at least a first functional operation and a second functional operation of the intended target appliance."

Issue(s)

- Would a POSITA have understood the prior art's disclosure of a listing of remote command codes formatted for transmission via two different communications methods to be a listing comprised of at least a first communication method and a second communication method different than the first communication method?

Holding(s)

The Federal Circuit found substantial evidence supported the Board's finding that a POSITA would not have understood the prior art's disclosure to be "a listing comprised of at least a first communication method and a second communication method different than the first communication method" and affirmed the Board.

Reasoning

The Federal Circuit agreed with the Board and found support from the specification and the expert's testimony. The '853 patent describes its listing as a "command matrix," comprising "a series of data cells" that include "identification of a form of command/transmission to be used" and "a pointer to the required data value and formatting information for the specific command," which is stored in a separate location in memory. The Court determined that "the patent specification itself distinguishes a list of communication methods from a separate list of command codes." The expert also testified that a skilled artisan "would not have understood a 'command code' to be a communication method." The Court found that the Board was entitled to weigh the evidence, and acknowledged that "although this court could well have decided the factual dispute at hand differently than the Board did, it is not the province of this court to do so," based on a substantial evidence standard.

UCB, Inc. v. Actavis Laboratories UT, Inc.

No. 2021-1924 (Fed. Cir. Apr. 12, 2023)

By: Don Geiger

Topic

This case addresses the legal framework for determining whether prior art anticipates a claimed range. The appropriate legal framework applies a different test depending on whether the prior art discloses a point within the claimed range vs. a range overlapping the claimed range.

Background

UCB, Inc. ("UCB") holds patents (the "Muller" patents, priority date in 1999) covering the active ingredient rotigotine in Neupro, a Parkinson's medication administered via a patch on the skin. The effectiveness of patch-administered rotigotine dips significantly if the rotigotine crystalizes, preventing its passage out of the patch and through the skin. Neupro's original formula contains a mixture of an additive polyvinlpyrrolidone ("PVP") to prevent crystallization of Neupro. The Muller patents disclose ratios of rotigotine to PVP ranging from 9:1.5 to 9:5. Neupro's original formulation has a rotigotine to PVP ratio of 9:2.

Actavis Laboratories UT, Inc. ("Actavis") submitted an ANDA application for approval of a generic version of Neupro's original formulation in 2013. In 2014, UCB sued Actavis for infringement of the Muller patents. UCB prevailed in the lawsuit, and was awarded an injunction against Actavis until March 2021, when one of the Muller patents expires.

In 2018, UCB filed a new patent application (the "'589 patent", priority date 2009) covering a reformulation of Neupro. The reformulated Neupro has a rotigotine to PVP ratio of 9:4, and the '589 patent claims a range of rotigotine to PVP ratios from 9:4 to 9:6.

In 2019, UCB again sued Actavis, this time asserting Actavis' 2013 ANDA application infringed the '589 patent. The District Court applied *Kennametal's* "at once envisage" test to find the '589 patent invalid as anticipated by the Muller patents. The District Court also found the '589 patent invalid as obvious in view of multiple prior art references, including the Muller patents.

UCB appealed the District Court's invalidity findings. Judge Stoll writes the opinion for the Federal Circuit.

Issue(s)

- Did The District Court err in applying *Kennametal's* "at once envisage" test when analyzing anticipation of a claimed range by a prior art disclosure of an overlapping range?

Holding(s)

The District Court's application of *Kennametal's* "at once envisage" test to analyze anticipation of the '589's claimed range by the Muller patents' disclosure of an overlapping range was erroneous.

While the District Court's finding of invalidity based on anticipation was erroneous, its finding of invalidity based on obviousness was not clearly erroneous. As such, the District Court's finding of invalidity was affirmed.

Reasoning

The correct legal framework (referred to herein as the *Ineos* legal framework) to analyze anticipation of a claimed range is as follows:

- **If the prior art discloses a point within a claimed range, the prior art anticipates the claimed range**. *Ineos USA LLC v. Berry Plastics Corp., 783 F.3d 865, 869 (Fed. Cir. 2015) (citing Titanium Metals Corp. v. Banner, 778 F.2d 775, 782 (Fed. Cir. 1985)).*
- **If the prior art discloses a range overlapping a claimed range, the prior art only anticipates the claimed range if it describes the claimed range with sufficient specificity such that a reasonable fact finder could conclude that there is no reasonable difference in how the invention operates over the ranges**. *Ineos USA LLC v. Berry Plastics Corp., 783 F.3d 865, 869 (Fed. Cir. 2015) (citing Atofina, 441 F.3d at 999; ClearValue, Inc. v. Pearl River Polymers, Inc., 668 F.3d 1340, 1345 (Fed. Cir. 2012)).* **Once a patent challenger has established, through overlapping ranges, its prima facie case of anticipation, the court must evaluate whether the patentee has established the claimed range is critical to the operability of the claimed invention**. *Genentech, Inc. v. Hospira, Inc., 946 F.3d 1333, 1338 (Fed. Cir. 2020) (quoting Ineos, 783 F.3d at 871).*

The Federal Circuit opinion included the figure below to illustrate how the claimed range overlaps with the Muller patents' disclosed range:

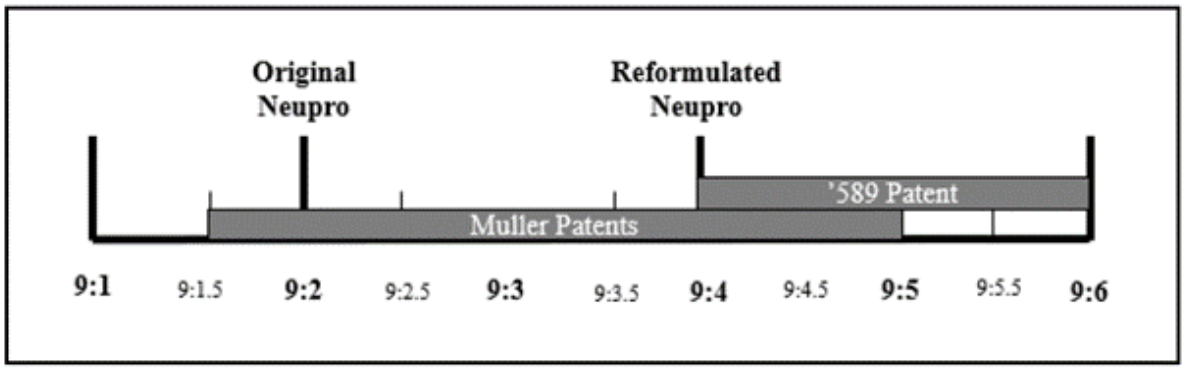


Figure 1: Asserted patent '589's claimed range vs. prior art Muller Patents disclosed range.

The Federal Circuit found the District Court's application of *Kennametal's* "at once envisage" test to analyze anticipation of the '589's claimed range by the Muller patents' disclosure of an overlapping range, erroneous. Under *Kennametal's* "at once envisage" test, a reference can anticipate a claim "even if it 'does not expressly spell out' all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination." 780 F.3d at 1381.

The Federal Circuit held the District Court should have instead applied the *Ineos* legal framework (above) to first find a prima facia case of anticipation established by the undisputed ranges, and then looked for a showing of criticality of the '589 patent's claimed range to the invention in the '589 patent.

The Federal Circuit declined to rule on the criticality of the claimed range, as the '589 patent was still found to be invalid based on the District Court's finding of obviousness.

Amgen Inc. v. Sandoz Inc

No. 2022-1147 (Fed. Cir. Apr. 19, 2023)

By: Zijian Han

Topic

This case is an appellate review of the district court's findings regarding patent obviousness and priority date.

Background

Amgen produces and markets apremilast, a medication for the treatment of certain types of psoriasis and psoriatic arthritis, under the brand name Otezla. Amgen also owns three patents — the '638, '101, and '541 patents — covering Otezla. Sandoz submitted an Abbreviated New Drug Application (ANDA) seeking approval to market a generic version of apremilast. Celgene, the prior owner of the asserted patents, then sued Sandoz for infringing them, and Amgen was substituted as plaintiff when Celgene transferred to Amgen these three patents. The district court (District of New Jersey) held that the asserted claims of the '638 and '101 patents were not invalid as obvious and that the asserted claims of the '541 patent were invalid as obvious.

Both Amgen and Sandoz appealed. Regarding the '638 patent, Sandoz argued that the district court erred in failing to find a motivation to isolate apremilast from a known racemic mixture and also for failing to find a reasonable expectation of success in separating the mixture. Regarding the '101 patent, Sandoz argued that the district court erred in holding that the '515 provisional application inherently disclosed the crystalline Form B of apremilast and thus that it did not provide the necessary written description support to entitle the patent to a March 2002 priority date. Regarding the '541 patent, Amgen argued that the district court erred in holding that the claimed dose-titration schedule would have been obvious.

Issue(s)

- Is the '638 patent invalid as obvious given objective indicia of non-obviousness?
- Did the '515 provisional application provide necessary written description support to entitle the '101 patent to a March 2002 priority date?
- Would the claimed dose-titration schedule in the '541 patent have been obvious?

Holding(s)

- No. The '638 patent is not invalid as obvious given objective indicia of non-obviousness.
- Yes. The '515 provisional application provides the necessary written description support to entitle the '101 patent to a March 2002 priority date.
- Yes. The claimed dose-titration schedule in the '541 patent would have been obvious.

Reasoning

The Federal Circuit found no clear error in the district court's holding that Sandoz did not meet its burden of establishing that the prior art gave a skilled artisan reason or motivation to isolate apremilast from a known racemic mixture, i.e., to resolve the racemic mixture into its enantiomers. The Federal Circuit held that the district court properly credited both parties' experts and found Amgen's expert to be more persuasive. Amgen's expert had provided information establishing that resolving a racemic mixture is a difficult process based on trial-and-error experimentation with many possible options for the solvent system at the time.

As for the objective indicia, the Federal Circuit affirmed that the trial record established the presence of unexpected results, including testimony from a researcher listed as an inventor on the '638 patent, stating that they did not expect a 20-fold difference in potency between apremilast alone and the apremilast containing racemic mixture. The Federal Circuit also credited other objective indicia, each supported by expert testimony, such as long-felt need, failure of others in the field, and industry and regulatory skepticism.

The Federal Circuit found that crystalline Form B of apremilast is actually disclosed in the '515 provisional application, which provided support for relevant claims in the '101 patent to be entitled to a March 2002 priority date. The Court noted that Amgen provided over a dozen of experiment results to show the procedure in Example 2 of the '515 provisional application resulted in crystalline Form B of apremilast and that Sandoz provided no evidence to show that the procedure "may have been capable of producing a crystalline Form other than Form B." The Court further held that it did not need to reach the issue of inherent disclosure because inherency is not required given the experiment results and expert testimony.

The Federal Circuit affirmed the district court ruling that credited Sandoz's expert testimony that titrating doses to treat a patient with psoriasis is well within a skilled artisan's ability. The Court agreed that modifying the dosing schedule (dose titration) taught in a prior art reference would have been obvious to a skilled artisan. The Court found that when prescribing drugs with known dose-dependent adverse events in the early weeks of treatment, a skilled artisan would have been motivated to use the prior art schedule "as a starting point and extend it to titrate the dosing up in smaller amounts." Thus, citing *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1376–77 (Fed. Cir. 2022), the Federal Circuit held that varying a dose in response to the occurrence of side effects is well-known and obvious to the skilled artisan.

Sanofi-Aventis Deutschlan GMBH v. Mylan Pharmaceuticals Inc.

No. 2021-1981 (Fed. Cir. May 9, 2023)

By: Sofya Asatryan

Topic

The Federal Circuit reversed a Patent Trial and Appeal Board ("Board") decision finding the challenged claims of Sanofi-Aventis' '614 patent unpatentable as obvious.

Background

Mylan petitioned for *inter partes* review of Sanofi-Aventis' '614 patent, alleging that the challenged claims were obvious based on a combination of three prior art references: Venezia, Burren, and de Gennes. The parties agreed that the '614 patent and the de Gennes reference belonged to distinct fields of endeavor.

Mylan's obviousness argument relied on demonstrating that each prior art reference it applied in its asserted obviousness combination constituted analogous art. Instead of showing that de Gennes was pertinent to the problem faced by the inventor of the challenged patent, Mylan argued that de Gennes constituted analogous art because it was pertinent to a problem faced by the Burren reference. The Board concluded that Burren, in combination with Venezia, did not render the challenged claims unpatentable but found the '614 patent unpatentable as obvious in view of the three prior art references. Specifically, the Board found that de Gennes constituted analogous art to the '614 patent. Sanofi argued on appeal that the Board erroneously agreed with Mylan's argument that de Gennes constituted analogous art because Mylan incorrectly compared the de Gennes reference to another prior art reference, and not the '614 patent. Sanofi further argued that the Board improperly shifted the burden of persuasion from Mylan to prove that the challenged claims were unpatentable to Sanofi to defend the claims of the '614 patent as patentable.

Issue(s)

- Whether the Board erred in finding that de Gennes constituted analogous art to the '614 patent and, thus, was properly combined with Venezia and Burren to render the '614 patent's claims obvious.

Holding(s)

The Federal Circuit reversed the Board's obviousness finding because Mylan failed to establish that the primary prior art reference, de Gennes, is analogous to the '614 patent.

Reasoning

Sanofi argued to the Board that de Gennes is not analogous to the '614 patent, whereas Mylan incorrectly argued that de Gennes was analogous to *another prior art reference* and not the challenged patent. A reference constitutes analogous art if either (1) the reference is "from the same field of endeavor, regardless of the problem addressed" or (2) "the reference is reasonably pertinent to the particular problem with which the inventor is involved," even if it is from a distinct field of endeavor. In determining whether a reference is analogous, the reference must be compared to the challenged patent. As such, Mylan's attempt to characterize de Gennes as analogous art based on its similarity to another prior art reference was improper, and thus, did not support its obviousness arguments. The Board, therefore, erred in finding the '614 patent obvious based on de Gennes.

Medtronic et al. v. Teleflex Innovations

No. 2021-2357 (Fed. Cir. June 5, 2023)

By: Fred Chung

Topic

In this case, the Federal Circuit determined the sufficiency of evidence to rebut a nexus between objective evidence and non-obviousness; and to establish the objective indicia of copying.

Background

Medtronic petitioned for *inter partes* review of U.S. Patent Nos. 8,048,032; RE45,380; and RE45,776 that cover catheters to treat stenosis, that is, a narrowing of the lumen of a patient's arteries due to the buildup of plaque. In the IPR proceeding, Teleflex opposed the prior art grounds as not achieving the alleged benefits of the prior art combinations without additional modifications. Teleflex also cited secondary considerations of non-obviousness, including alleging that Medtronic had copied Teleflex's Guideliner product that embodied the claims; that GuideLiner was copied by other competitors; enjoyed a high level of commercial success, received significant praise in the industry, and solved long-felt needs within the medical community for catheters with increased back-up support. Medtronic appealed the Board's decision as to the claims that recite a side opening and were held to not be obvious.

Issue(s)

- Whether the Ressemann reference disclosed the combination of features as to preclude a nexus between the objective evidence of non-obviousness.
- Whether the Board's silence on Ressemann's lack of the missing feature established that Ressemann disclosed the missing feature.
- Whether the circumstantial evidence of copying, in lack of evidence of direct efforts to copy, was insufficient to find that Medtronic had copied Teleflex's product.

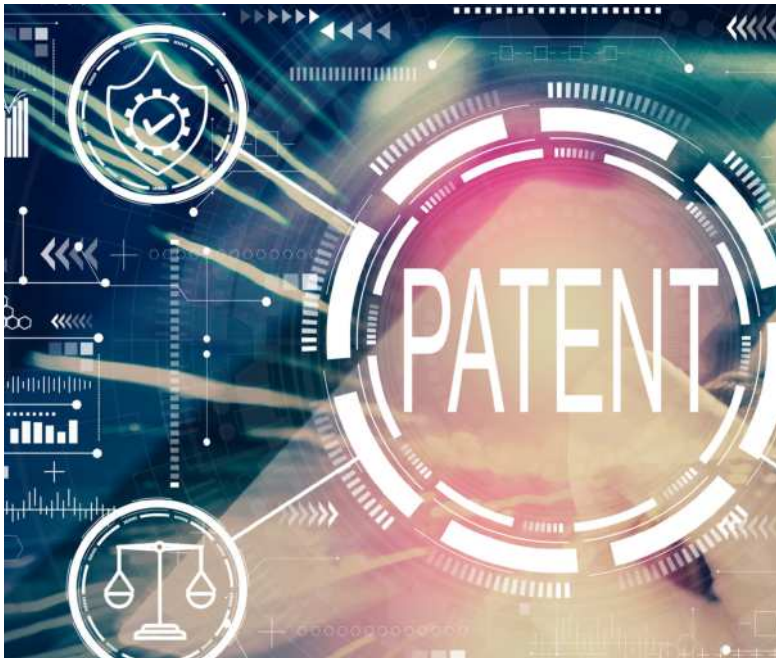
Holding(s)

- Teleflex's evidence of objective indicia of non-obviousness had a nexus to the Side Opening Claims.
- Medtronic failed to make a showing that objective evidence resulted from features that were known as a combination in the prior art.
- The Board's analysis of the nexus was legally correct and supported by substantial evidence.
- Direct evidence of copying is not necessary to establish copying.
- The Board's finding of copying is supported by substantial evidence.
- The totality of objective indicia support a finding of non-obviousness.

Reasoning

The Federal Circuit found that the presumption of nexus applies because it was undisputed the asserted objective evidence was tied to a specific product, and Medtronic failed to rebut the presumption. While the Board acknowledged that Medtronic had shown that each limitation was known individually – this alone did not prevent a finding of nexus based on the combination of features as a whole – and the Federal Circuit found no errors in the Board's legal analysis.

Medtronic's argument that the Board made legal error based on a prior art reference that in Medtronic's view disclosed the combination of features upon which the nexus argument was based incorrectly casts a disagreement with the Board's fact finding as legal error.



Both Teleflex and the Board relied on the combination of a side opening with coaxial lumens. Medtronic's argument that the Board's reliance on the coaxial lumens is irrelevant because the Board never made any finding distinguishing the side opening from the Ressemann prior art reference incorrectly shifts the burden. In an IPR, Medtronic as the petitioner has the burden of proving unpatentability. The absence of a finding that Ressemann does not have a coaxial lumen cannot establish that Resseman has that feature.

Finally, Medtronic did not dispute that the Board's decision of finding a nexus, if legally proper, was supported by substantial evidence.

With respect to objective indicia of copying, the Federal Circuit disagreed with Medtronic and found that evidence of access and substantial similarity is at least circumstantial evidence of copying. It was undisputed that the Guideliner product was available to the public and on the market at the time Medtronic was developing its extended catheter product. The Board found Teleflex's expert's testimony on substantial similarity persuasive. The Federal Circuit found Medtronic's argument that the Board committed legal error by relying on evidence of substantial similarity meritless.

Medtronic, Inc., Medtronic Vascular, Inc., v. Teleflex Innovations S.A.R.L.

No. 2021-2359 (Fed. Cir. June 5, 2023)

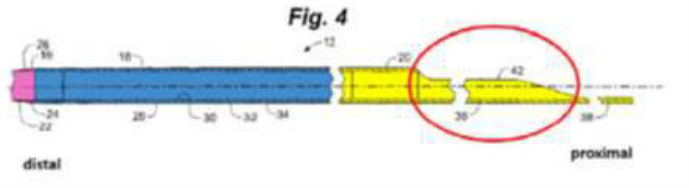
By: Don Geiger

Topic

This case addresses the weight the Patent Trial and Appeal Board (PTAB) should give to the intended purpose of a primary reference when evaluating a Person of Ordinary Skill in the Art's (POSITA) motivation to combine that primary reference with secondary references.

Background

Teleflex Innovation S.A.R.L. (Teleflex) owns multiple patents to a dual catheter design, wherein an extension catheter is disposed within a larger guide catheter coaxially. This coaxial orientation allows the larger guide catheter to remain relatively stationary and secure within a patient's artery while the extension catheter within is free to extend through the guide catheter into the patient. Teleflex's patent is specific to the context of delivering interventional cardiology devices (e.g., guidewires, stents, stents, balloon catheters) into a patient's coronary artery. The opinion provides Fig. 4 from one of Teleflex's patents for describing the extension catheter in Teleflex's invention:



Pink region 16, indicated at the extension catheter's distal end, comprises a flexible tip, such that the distal end's imposition with a coronary artery is less likely to cause damage. Blue region 18 is disclosed as reinforced, such that it can actuate through the more rigid guide catheter without kinking. Yellow region 20 is disclosed as a "substantially rigid" portion located at the extension catheter's proximal end (the end disposed outside the patient, where the physician would introduce interventional cardiology devices). Teleflex's patents include limitations to the

angled "side opening" design (circled in red), allowing for a greater "entry area" (i.e., the area where a physician can insert devices).

Medtronic, Inc. and Medtronic Vascular, Inc. (collectively, Medtronic) filed IPR petitions, challenging the Teleflex patents on obviousness grounds. Medtronic asserted Ressemann, which discloses a device for evacuating embolic material while occluding blood flow using sealing balloons, in combination with multiple secondary references, including Takahashi. Takahashi discloses a dual catheter design for delivering interventional cardiology devices into a patient's coronary artery, which is a purpose shared with the Teleflex patents.

The PTAB issued final written decisions holding some claims unpatentable as obvious and others not unpatentable. The PTAB reasoned that some claims are not unpatentable because Medtronic's proposed modifications of Ressemann with Takaheshi would have rendered Ressemann "completely inoperable" for its stated purpose. In addition, the PTAB granted Teleflex's contingent motion to amend certain claims, and also determined that the substitute claims were not unpatentable. Medtronic appealed the determination of patentability and the substitute claims to the Federal Circuit.

Issue(s)

- Did the PTAB err in finding no motivation to combine Ressemann with Takaheshi, where the proposed combination would have rendered Ressemann completely inoperable for Ressemann's stated purpose?

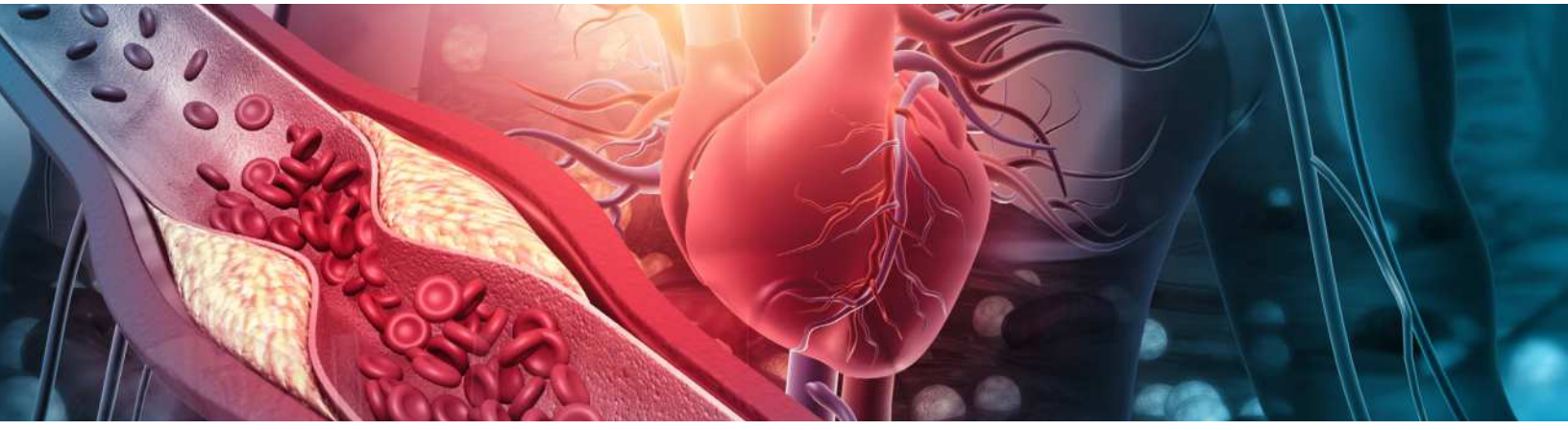
Holding(s)

The PTAB did not err in finding no motivation for a POSITA to combine Ressemann with Takaheshi, where the proposed combination would have rendered Ressemann completely inoperable for Ressemann's stated purpose. Notably, even though the Federal Circuit had previously held in *Intel Corp. v. Qualcomm Inc.*, 21 F. 4th 784, 800-01 (Fed. Cir. 2021) that the intended purpose of a reference does not control the obviousness inquiry, the intended purpose of that reference may nonetheless be probative in considering a motivation to combine. As such, the PTAB did not err in considering the proposed combination's conflict with Ressemann's intended purpose when finding no motivation to combine. The PTAB's findings of non-invalidity are affirmed.

Reasoning

The *Intel* case stands for the proposition that the intended purpose of a reference is not dispositive of whether a POSITA would have had motivation to combine the reference. ***Intel* does not stand for the proposition that the intended purpose of a reference is legally irrelevant to obviousness.**

Here, the intended purpose of the primary reference, Ressemann was relevant because, in forming the proposed combination with Takeshi, one would have been required to modify Ressemann in a manner that would have destroyed Ressemann's entire purpose and potentially introduced safety concerns. As such, the proposed combination was simply not feasible.



Yita LLC v. MacNeil IP LLC

Nos. 2022-1373, 2022-1374 (Fed. Cir. June 6, 2023)

By: Li Guo

Topic

This decision addresses the PTAB's secondary considerations analysis in an IPR Final Written Decision.

Background

Appellant Yita sought *inter partes* review of two patents sharing a specification, both of which are directed to the vehicle floor tray. In one IPR, the Board determined that claims of one patent (the '186 patent) were not unpatentable for obviousness. The Board determined that there was a motivation to combine and reasonable expectation of success in combining the prior art references to arrive at the claimed inventions but rejected Yita's obviousness challenge because Appellee MacNeil's secondary-considerations evidence was compelling and indicative of non-obviousness.

In the other IPR (involving the '834 patent), the Board found certain claims unpatentable for obviousness and found unpersuasive MacNeil's secondary-considerations evidence, which Yita had argued without dispute from MacNeil was identical to the secondary-considerations evidence in the IPR involving the '186 patent. The Board found that this evidence focused on features not recited in these claims. Regarding the other challenged claims, the Board rejected Yita's challenge at the prima-facie stage of analysis, finding that a particular limitation was not disclosed by any of the asserted prior art references. In relying on that finding to hold the prima-facie case unpersuasive (making secondary considerations immaterial for these claims), the Board declined to consider an argument that Yita raised in a footnote in its Reply brief, finding that argument outside the scope of a proper reply. Yita appealed both Final Written Decisions, arguing with respect to the first IPR that the Board made a results-determinative legal error regarding MacNeil's secondary-considerations evidence in rejecting Yita's obviousness challenge, and with respect to the second IPR that the Board abused its discretion by not considering its foot-note argument.

On appeal, the Federal Circuit sided with Yita on its first argument but rejected Yita's second argument.

Issue(s)

- Did the Board err in its decision regarding MacNeil's secondary-consideration evidence in rejecting Yita's challenge to the claims of the '186 patent?
- Was there abuse of discretion in the Board's decision not to consider the new foot-note argument Yita made?

Holding(s)

- The Board legally erred in its secondary considerations analysis.
- There was no abuse of discretion in the Board's decision.

Reasoning

The decision first sets forth the legal standard regarding obviousness, including secondary considerations. Namely, that secondary considerations include whether the claimed invention has been commercially successful, whether it solved a long-felt but unsolved need in the art, and whether the relevant industry praised it. To be relevant, secondary considerations must have a legally and factually sufficient connection (nexus) to the claimed invention. A

nexus is presumed when a commercial product (if relevantly successful, for example) is the invention disclosed and claimed in the patent.

Regarding issue (1), the Federal Circuit found that the Board's finding of a nexus rested on legal errors, and once those errors are corrected, the finding is not supported by substantial evidence. ***First***, the Board stated that its finding regarding Rabbe's (one of the three prior art references Yita relied on) disclosure does not establish that close conformance (a key feature recited by the challenged patent) was "well-known," as Yita contended. The Federal Circuit explained, however, that its case law makes clear that objective evidence of non-obviousness lacks a nexus if it exclusively relates to a feature that was "known in the prior art"—not necessarily well-known. Where prior art teaches a feature and a relevant artisan would have been motivated to use it in combination with other prior-art teachings with a reasonable expectation of success to arrive at the claimed invention—as the Board found below—a secondary consideration related exclusively to that feature does not logically undermine the inference from those premises that the claimed invention would have been obvious from the full body of prior art just because the feature was not *well*-known.

Second, the Board, citing *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317 (Fed. Cir. 2016), stated that the Federal Circuit instructs that it is the claimed combination as a whole that serves as a nexus for objective evidence; proof of nexus is not limited to only when objective evidence is tied to the supposedly new feature(s). But in the present appeal the Federal Circuit explained that in *WBIP* it recognized that secondary-consideration evidence may be linked to an individual element of the claimed invention or to the inventive combination of known elements in the prior art. The Federal Circuit further explained that it was for the latter circumstance, which was the circumstance present in *WBIP*, that it, in *WBIP*, made the point relied on by the Board below. But that rationale is applicable only when no single feature (but only the combination) is responsible for the second consideration and a secondary consideration that is exclusively related to a single feature that is in the prior art has no force. Here the Federal Circuit found, the Board's finding that MacNeil's secondary-consideration evidence "relate[d] entirely" to the close-conformance limitation disclosed in the prior art compels the conclusion that MacNeil's secondary-consideration evidence is irrelevant to obviousness. Further, the Federal Circuit noted that the Board's finding that the WeatherTech floor tray is coextensive with the claimed invention does not alter the result because the coextensiveness inquiry bears only on the presumption of nexus; it does not decide the overall nexus question. And the presumption inquiry compares only the claim with the commercial product. It does not involve the connection between the commercial product and prior art, which governs the final nexus question and here is the decisive problem for MacNeil.

In sum, the secondary-consideration evidence was the only *Graham* factor that the Board deemed to weigh in favor of non-obviousness. For the reasons explained, the finding of secondary considerations lacks substantial-evidence support under the proper legal standard.

Regarding issue (2), the Federal Circuit concluded that there was no abuse of discretion in the Board's decision because Yita could have presented its reply argument in its Petition but chose not to, and the patent owner's response did not justify the new argument in reply. In particular, the Federal Circuit analogized Yita's argument to the one addressed in the Federal Circuit's decision in *Intelligent Bio-Systems*—where the petitioner argued in the petition that the prior art disclosed a claim limitation but then in its reply brief argued that the reference would be modified to disclose the limitation. The modification argument, the Federal Circuit explained, is meaningfully distinct from the argument in the petition, which focused only on what the reference discloses. Further, Yita was unable to identify where in the Patent Owner Response MacNeil made an argument about what a relevant artisan would have found obvious to modify in the prior art reference. Thus, the Federal Circuit held that Yita's argument was not justified and therefore the Board did not abuse its discretion.

In Re: Couvaras

No. 2022-1489 (Fed. Cir. June 14, 2023)

By: Joshua Weisenfeld

Topic

This case addresses obviousness under 35 U.S.C. § 103 in relation to a method of increasing prostacyclin release to reduce hypertension in a patient. In particular, this case discusses issues relating to motivation to combine, unexpected results, and objective indicia of non-obviousness.

Background

John L. Couvaras filed U.S. Patent Application 15/131,442 (the "'442 Patent") with claims directed to a method of increasing prostacyclin release in systemic blood vessels of a human to improve vasodilation and reduce hypertension. Such method claims were directed to the application of a combination of GABA-a agonist and ARB. During prosecution, Couvaras conceded that GABA-a agonists and ARBs have been known for "many, many decades," but asserted that the prostacyclin increase was unexpected, and therefore should be patentable. Couvaras appealed the final rejection on the matter to the Patent Trial and Appeal Board ("Board"), which affirmed the rejection and held that the "claimed result of an increased prostacyclin release was inherent in the obvious administration of the two known antihypertension agents." Further, the Board found that Couvaras's objective indicia arguments did not overcome the prima facie case of obviousness because no evidence existed or was presented to support such a finding. Couvaras then appealed the Board's decision to the Federal Circuit.

Issue(s)

- Whether there is motivation to combine prior art disclosing two different antihypertension agents.

- Whether the Board sufficiently weighed objective *indicia* of nonobviousness, including unexpected results, teaching away, the failure of others, and the length of time that elapsed between the initial discovery of the hypertension agents and the claimed method.

Holding(s)

The Federal Circuit held that the Board did not err in finding that a skilled artisan would have a motivation to combine the prior art references cited by the examiner during prosecution.

The Federal Circuit held that the Board did not err in finding that the recitation of various mechanistic steps in the pending claims were insufficient to overcome the prima facie obviousness of the claimed methods.

Reasoning

In affirming the Board's conclusion that a motivation to combine existed to render the invention obvious, the Federal Circuit focused on the fact that both GABA-a agonists and ARBs were known to be useful in the treatment of hypertension. Additionally, Couvaras conceded that the prior art teaches both the combination of ARBs with other antihypertensive agents to improve treatment and the use of ARBs "in combination with other classes of antihypertensive agents to lower blood pressure." Couvaras attempted to argue that even if the prior art provided a motivation to co-administer two hypertension treatments, the Board failed to identify a "finite number of identified, predictable solutions" as required under *KSR*. The Federal Circuit rejected this argument on both procedural and substantive grounds. Procedurally, the argument was raised by Couvaras in a footnote, and the Federal Circuit cited *Otsuka Pharm. Co.* to note that "[a]rguments raised only in footnotes [] are waived." *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1294 (Fed. Cir. 2012). Substantively, the Federal Circuit noted that Couvaras did not present any evidence to the Board supporting the argument that there are a "'substantial number of hypertension treatment agent classes' that could be considered for such a combination," while the Board's decision was based on substantial evidence in light of the prior art suggesting a motivation to combine.

Couvaras argued that the Board incorrectly determined that the antihypertensive agents' mechanism of action was inherent. Even if the recited mechanism is inherent, argued Couvaras, the increased release of prostacyclin was unexpected, and thus the limitations cannot be dismissed as having no patentable weight due to inherency. The Federal Circuit rejected this argument, relying on *In re Montgomery*,

677 F.3d 1375, 1381 (Fed. Cir. 2012) to point out that "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." The prostacyclin mechanism may have been an unexpected result, but it "exert[s] the same ultimate result as the two separate compounds were known to effect: a decrease in blood pressure." In sum, the Federal Circuit explained that "[r]eciting the mechanism for known compounds to yield a known result cannot overcome a prima facie case of obviousness, even if the nature of that mechanism is unexpected."

Similarly, the Federal Circuit rejected Couvaras's argument that the Board erred by finding that the result of the claimed invention was unexpected, but nonetheless failed to give any weight to the unexpected results *indicium* of nonobviousness. As explained by the Federal Circuit, the focus of the unexpected results inquiry is an "unexpected benefit." That is, for Couvaras to establish unexpected results, he would have needed to show "better control of hypertension, less toxicity to patients, or the ability to use surprisingly low dosages," none of which he did.

With respect to teaching away, Couvaras argued that the prior art taught away from the combined administration that was recited in the claims. Rejecting this argument, the Federal Circuit pointed out that the alleged "teaching away" involved a reference combining different agents than claimed by Couvaras, agents that "operate through different biological mechanisms" rendering the equivalency useless for the purposes of arguing that a prior art reference "teaches away."

With respect to the "failure of others to increase prostacyclin release," the Federal Circuit quickly dispensed with Couvaras's argument, noting that evidence showing an "investigation into the impact of angiotensin II levels is not a failure to find a solution for an inability to increase prostacyclin release or a failure of the claimed method."

With respect to the length of time between the publication dates of the prior art and the claimed invention, the Federal Circuit relied on *Leo Pharm. Prod., Ltd. V. Rea*, 762 F.3d 1346 (Fed. Cir. 2013) to reason that Couvaras's reliance on the length of time was not sufficient without additional indicia of nonobviousness such as long-felt but unresolved need and failure of others, which were not present in this case.

Axonics v. Medtronic

No. 2022-1451 (Fed. Cir. July 10, 2023)

By: Sofya Asatryan

Topic

The Federal Circuit vacated and remanded two Patent Trial and Appeal Board ("PTAB") decisions because the PTAB erred in its obviousness analysis and found that Axonics failed to show a motivation to combine as to Medtronic's '314 and '756 patents.

Background

Medtronic sued Axonics for patent infringement. Medtronic's invention concerns a medical device that stimulates sacral nerves. Axonics filed two *inter partes* review (IPR) petitions to challenge various claims of the U.S. Patent Nos. 8,626,314 and 8,036,756 ("the Medtronic Patents") for obviousness under 35 U.S.C. §§ 311-319. No claim of the Medtronic Patents is limited to sacral nerves. Axonics argued that the Medtronic Patents were invalid based on preexisting patents and other publications that disclosed the same technology, particularly Young and Gerber. Both of Axonics' petitions relied on the same combination of Young and Gerber.

The PTAB ruled for Medtronic, finding that Axonics failed to show a motivation to combine. It concluded that Axonics failed to show that a relevant artisan would have a motivation to combine the teachings of Young and Gerber because the proposed combination "would not be feasible in the trigeminal nerve region." The Board reached that finding by defining the relevant art as limited to medical leads for sacral-nerve stimulation. Axonics appealed under 35 U.S.C. § 142 and 37 C.F.R. § 90.3(a)(1).

Issue(s)

- Did the PTAB err in confining its motivation-to-combine inquiry to what would work in the trigeminal nerve context?; and
- Did the PTAB err in limiting its definition of the relevant art to medical leads specifically for sacral neuromodulation?

Holding(s)

The Federal Circuit vacated and remanded the PTAB's decisions finding that: (1) the PTAB adopted a legally incorrect framing of the motivation-to-combine inquiry when it confined the inquiry to whether a motivation would exist to make the Gerber-Young combination for use in the Young-specific trigeminal-nerve context; and (2) the PTAB erred in its definition of the relevant art as being limited to medical leads for sacral-nerve stimulation.

Reasoning

First, the Board committed a fundamental error in confining the motivation inquiry to whether a motivation would exist to make the proposed combination for use in the Young-specific trigeminal-nerve context because the Medtronic Patents are not limited to that context. The "real question" is "why a person of ordinary skill in the art would have combined elements from specific references in the way the *claimed invention* does." Second, the PTAB was incorrect in limiting the definition of "the relevant art" to medical leads for sacral-nerve stimulation because the Medtronic patent claims are not so limited. In fact, they make no reference to sacral neuromodulation.

Rembrandt Diagnostics, LP v. Alere, Inc.

No. 2021-1796 (Fed. Cir. Aug. 11, 2023)

Forfeiture & Obviousness

By: Li Guo

Topic

This decision addresses the Patent Trial and Appeal Board's obviousness determinations in an *inter partes* review proceeding (IPR2016-01502), where the Board held the claims in the challenged patents unpatentable as obvious in view of the asserted prior art.

Background

The dispute began in 2016 when Rembrandt sued Alere in district court for patent infringement. After Rembrandt sued, Alere filed an IPR petition challenging claims 1–6 and 9–15 of U.S. Patent No. 6,548,019 ("the '019 patent"), which is directed to test assay devices and methods for testing biological fluids. Alere argued the challenged claims would have been obvious over two combinations of prior art patents relating to assay testing devices: (1) U.S. Patent No. 5,656,502 ("MacKay") in view of U.S. Patent No. 5,985,675 ("Charm") or U.S. Patent No. 5,602,040 ("May") and (2) U.S. Patent No. 6,379,620 ("Tydings") in view of MacKay or U.S. Patent No. 5,500,375 ("Lee-Own").

The Board issued a final written decision ("FWD") in February 2018, finding that while MacKay anticipated claim 2, Alere failed to prove claims 3–5 were unpatentable. Alere appealed and the Federal Circuit affirmed the

Board's claim construction but remanded for the Board to consider all the challenged claims and grounds under *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

On remand, Alere filed a reply with an accompanying declaration from its expert, Dr. Robert Bohannon, responding both to Rembrandt's arguments and to the observations the Board raised in its original institution decision. In February 2021, the Board issued its post-FWD decision finding claims 2–6 and 10 unpatentable. Rembrandt appealed, arguing that the Board erred by relying on Alere's new theories asserted for the first time in its reply brief. The appeal focused on claims 3–6 and 10.

Issue(s)

- Whether the Board abused its discretion when it allegedly relied on Alere's new theories and evidence, and whether substantial evidence supports the Board's factual findings.

Holding(s)

The Federal Circuit affirmed the Board's decision.

Reasoning

Regarding the first issue—Alere's new theories—the Federal Circuit agreed with Alere that Rembrandt forfeited its argument that Alere offered new theories. Rembrandt contended that it objected to the IPR grounds on the first page of its brief where it stated that Alere "resorts to new theories in reply." The Federal Circuit first addressed Rembrandt's objection and held its generic objection was insufficient to constitute a proper objection—especially because Rembrandt expressly objected to other allegedly new theories without doing so for the theory in dispute. The Federal Circuit noted that it would be unfair to both the parties and the Board to read so broadly such a generic objection, when neither would have adequate notice of which theories are allegedly new. The Court noted this would be particularly problematic for the Board, as it "must make judgments about when a reply contention crosses the line from the responsive to the new."

The Federal Circuit next addressed Rembradnt's new-theories argument. Regarding claim 10, the Court found that Alere's reply argument discussing cost and time savings had a nexus to Rembrandt's prior argument and was responsive. The Court further found that by discussing time and cost savings as a form of efficiency, the reply also properly expands on and is a fair extension of Alere's previously raised efficiency argument. Regarding claims 3–6, the Federal Circuit found that Alere's reply argument was responsive to Rembrandt's arguments and the Board's observations. Namely, merely Alere disputed Rembrandt's contention that wicking material is fundamental to Tydings and explained that removing wicking material would further achieve Tydings' goals of inexpensive and easy manufacturing. In short, as the Court concluded, Alere's responsive reply arguments do not constitute new theories, and the Board did not abuse its discretion in considering them.

Regarding the second issue—substantial evidence—Rembrandt asserted that for MacKay in view of Charm or May, the references' disclosures fail to support the Board's finding that MacKay, Charm, or May accommodate multiple test strips. The Federal Circuit found Rembrandt's arguments center on the interpretation of disclosures from the prior art and the presence of motivation to combine. The Court noted that Rembrandt "cite[d] to no counter testimony from a qualified declarant to refute [Alere's expert]'s conclusions regarding how a skilled artisan could have interpreted the identified disclosures." The Court noted, based on its review of the record—particularly the express disclosure in the prior art and Alere's expert's credible testimony—there is evidence that "a reasonable mind might accept" "as adequate to support" the Board's factual findings. The Court reasoned that the Board was presented with "two alternative theories" about what the prior art discloses, and it is not the Federal Circuit's task "to determine which theory we find more compelling." Thus, the Court held the Board's obviousness determinations are supported by substantial evidence.

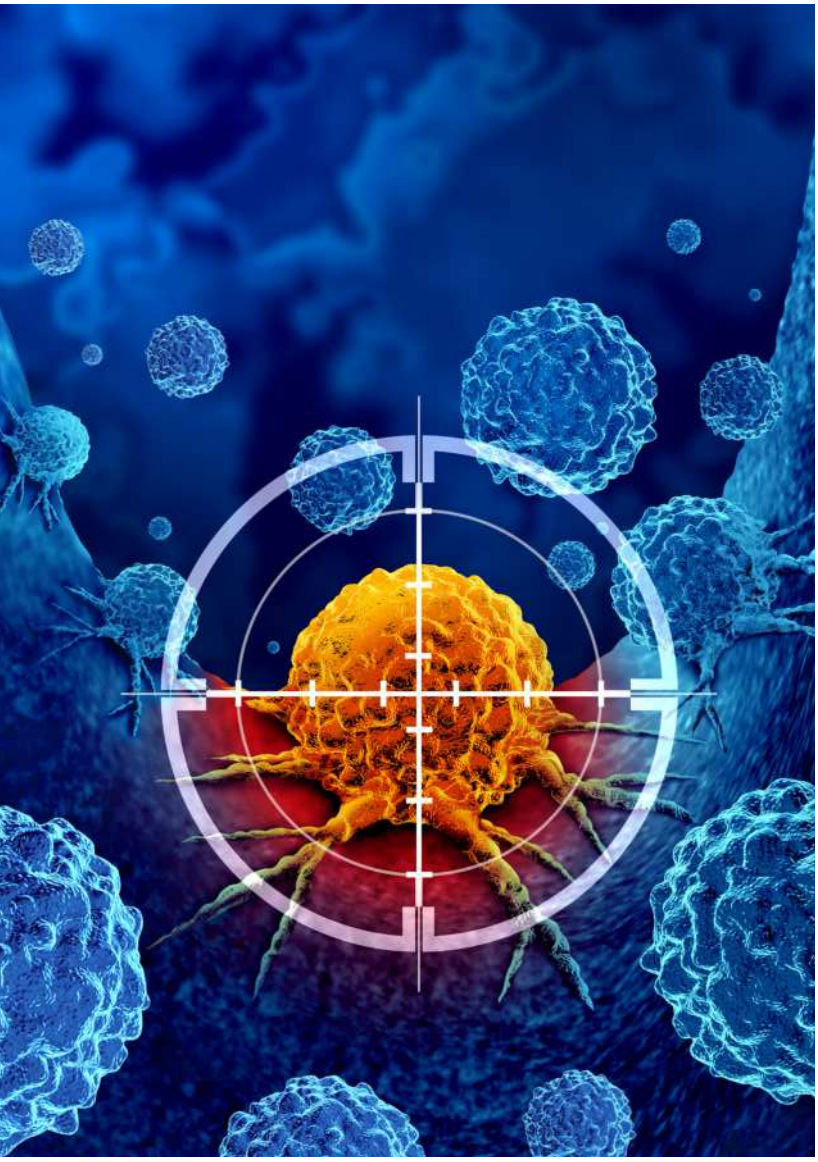
Incept v. Palette Life Sciences

No. 2021-2063, 2021-2065 (Fed. Cir. Aug. 16, 2023)

By: Li Guo

Topic

This case addresses the Board's anticipation and obviousness determinations in two IPRs (IPR2020-00002 and IPR2020-00004), where the Board held the claims in the challenged patents unpatentable as anticipated by, or obvious in view of, the asserted prior art.



Background

Palette Life Sciences, Inc. ("Palette") filed petitions for *inter partes* review challenging the claims of U.S. Patent Nos. 8,257,723 (the '723 patent) and 7,744,913 (the '913 patent) as unpatentable over prior art, including U.S. Patent No. 6,624,245 to Wallace et al. ("Wallace"). The challenged patents relate to improved methods for treating cancer, particularly prostate cancer, using radiation. The patents describe methods of introducing a filler between a radiation target tissue and other tissue to increase the distance between the two and thereby decrease the amount of radiation received by the non-targeted tissue.

Claim 1 of the '723 patent is reproduced as below:

- A method of delivering a therapeutic dose of radiation to a patient,
- introducing a biocompatible, biodegradable filler between an organ and a nearby tissue to increase a distance between the organ and the tissue, and
- treating the tissue with the therapeutic dose of radiation so that the presence of the filler causes the organ to receive less of the dose of radiation compared to the amount of the dose of radiation the organ would receive in the absence of the filler,
- wherein the filler is introduced as an injectable material and is a gel in the patient, and wherein the filler is removable by biodegradation in the patient.

Independent claim 1 of the '913 patent is similar to claim 1 of the '723 patent but includes the additional limitation that the filler is introduced specifically between a patient's prostate gland and rectum.

The Board instituted *inter partes* review and ultimately issued final written decisions in which it held that Palette had established the challenged claims to be unpatentable on the Wallace-based grounds set forth in the two petitions. Incept appealed.

Issue(s)

- Whether the Board's anticipation and obviousness determinations should be reversed.

Holding(s)

The Federal Circuit affirmed the final written decisions.

Reasoning

Regarding the Board's anticipation finding, Incept first argued on appeal that the Board committed legal error because it engaged in a "patchwork approach" that involved "picking and choosing" from Wallace's different teachings to piece together the elements of the '723 patent claims. Relying on *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1376 (Fed. Cir. 2006), Incept argued that when a prior art reference describes a genus and the challenged claim recites a species of that genus, anticipation turns on whether the genus was of such a defined and limited class that one of ordinary skill in the art could have "at once envisaged" each member of the genus. The Federal Circuit saw no legal error in the Board's anticipation analysis, and found that the Board did not engage in "picking and choosing" features from different teachings of Wallace but instead found that Wallace expressly describes compositions that have the claimed characteristics of, and are used for the same displacement purpose as, the compositions referred to in the '723 patent claims challenged as anticipated. Moreover, the Court noted that the claims of the '723 patent are not directed to a "species" of fillers that fall within the "genus" of compositions described in Wallace, but rather a method of introducing fillers having certain general qualities, which general qualities Wallace's compositions are also described as having. As the Court noted, "Incept cannot use the fact that Wallace describes multiple compositions to evade an anticipation finding where Wallace provides 'as complete detail as is contained in the patent claim,' such that a skilled artisan would have understood that Wallace's compositions had the same generic properties as those in the '723 patent claims."

Incept next took issue with what it referred to as the Board's failure to identify a teaching in Wallace that any of its compositions are "entirely removable by biodegradation." The Federal Circuit was not persuaded that the Board's finding of biodegradability was insufficient, noting that while an excerpt of Wallace alone constitutes substantial evidence to support the Board's finding, the finding is also supported by the testimony of Palette's expert that a skilled artisan would have appreciated that Wallace teaches that the filler is removable by biodegradation.

Incept next contended that the Board failed to identify a teaching in Wallace that any of its compositions are placed "between an organ and a nearby tissue," as required by the '723 patent claims. The Federal Circuit found the Board's related findings were supported by substantial evidence in the form of Wallace's teachings.

Regarding the Board's obviousness finding, Incept first argued that the Board's obviousness analysis for both patents was based entirely on its flawed anticipation analysis for the '723 patent claims. The Federal Circuit noted that it failed to see how the Board's reliance upon that analysis was in error as it found no error in the Board's anticipation analysis. The Federal Circuit also disagreed that the Board's obviousness analysis for the '913 patent was based entirely on its anticipation analysis for the '723 patent claims, and that the Board's findings of motivation to combine were not merely conclusory.

In an argument parallel to its argument regarding anticipation, Incept contended that the Board ignored that Wallace "taught away" from biodegradable compositions. The Federal Circuit disagreed and noted that in any event, a reference does not teach away if it merely expresses a general preference for an alternative invention but does not criticize, discredit or otherwise discourage investigation into the invention claimed (citing *UCB, Inc. v. Actavis Laby's UT, Inc.*, 65 F.4th 679, 692 (Fed. Cir. 2023)). The Court found that the portions of Wallace that Incept pointed to clearly lack such a teaching, therefore substantial evidence supports the Board's finding with respect to the scope of Wallace's teachings.

Incept next contended that the Board did not separately analyze certain dependent claims of the two patents. The Court rejected Incept's argument, noting that Palette identified disclosures in the prior art that teach each of the elements of these claims, and that Incept did not separately argue their patentability before the Board. The Court further noted that where a party does not raise any arguments with respect to any other claim limitation, or otherwise separately argue for the dependent claim, the dependent claim stands or falls together with the independent claim (citing *Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1340 (Fed. Cir. 2020)).

Incept finally argued that the Board erred in its obviousness analysis because it imposed an overly stringent standard for showing commercial success. The Federal Circuit noted that it saw no reversible error in that determination, whether viewed as a factual one about the level of success or a legal one about the weight of any such success in the overall obviousness analysis, and noted that the Board did not require Incept to provide market share data but instead weighed the evidence provided by Incept and merely found that evidence insufficient, alone, to show commercial success.

Volvo Penta of the Americas, LLC, v. Brunswick Corporation

No. 2022-1765 (Fed. Cir. Aug. 24, 2023)

By: Takuma Nishimura

Topic

In this case, Brunswick petitioned for an *inter partes* review of Volvo's U.S. Patent No. 9,630,692 patent ("the '692 patent") challenging all claims as obvious. Brunswick filed its challenge on the same day as the launch of its competing product – the Bravo Four S. The '692 patent relates to a stern-mounted motor design with forward, bow-facing propellers. It was undisputed that both Volvo and Brunswick have competing products that embody the '692 patent.

Background

Brunswick's challenge relied on two prior art references: (i) Kiekhaefer, a 1962 patent that is directed to an outboard motor that could have either a rear-facing or forward-facing propellers and (ii) Brandt, a 1989 patent directed to a stern-mounted drive with rear-facing propellers.

Volvo did not dispute that the combination of prior art references disclosed all claim limitations. Instead, Volvo argued that a person of ordinary skill in the art would not have been motivated to combine the references with a reasonable expectation of success and that objective indicia of nonobviousness overcame any prima facie case of obviousness.

The Board rejected Volvo's argument and found there was sufficient evidence of motivation to combine the two prior art references. Volvo appealed the Board's decision. Brunswick settled with Volvo after appeal briefing completed and the USPTO intervened to defend the Board's decisions relying on Brunswick's appeal briefing.

Issue(s)

- Was there substantial evidence to support the Board's finding of a motivation to combine the references?
- Was there a nexus between the claimed invention and the evidence of secondary consideration of nonobviousness?
- Did the Board sufficiently consider the secondary considerations of non-obviousness?

Holding(s)

- The Board's finding of a motivation to combine the references was supported by substantial evidence.
- The Board correctly found that Volvo's presumption of a nexus was not supported due to Volvo's lack of co-extensiveness argument, but the Board's finding of a lack of independent nexus was not supported by substantial evidence.
- The Board failed to properly analyze and consider the objective indicia of nonobviousness.

Reasoning

Motivation to Combine

Volvo argued that there was no motivation to combine based on (1) despite having knowledge of Kiekhaefer for decades, Brunswick never attempted the proposed modification; (2) Brunswick's proposed modification would have required a nearly total redesign of the drive system; (3) the complexity in shifting the vertical drive shaft of Kiekhaefer; and (4) Brunswick attempted and failed to create a functional front drive system. The Federal Circuit held all these factors were sufficiently considered and this issue was correctly decided. Furthermore, the Board correctly rejected Volvo's argument by holding that the existence of other designs to improve speed and efficiency does not make the selection of Kiekhaefer nonobvious. The Federal Circuit agreed with the Board that speed and efficiency were considered in the motor's design, but these considerations were not exclusive.

In summary, the Board correctly considered the record as a whole, despite its reliance on Volvo's witness who was **not** a person of ordinary skill in the art, and its finding of motivation to combine was supported by substantial evidence.

Nexus

For secondary consideration evidence to be relevant, there must be a nexus between the merits of the claimed invention and the secondary consideration evidence, which can be shown in two ways: (1) through a presumption of nexus, or (2) showing that the evidence is a direct result of the unique characteristics of the claimed invention.

A patent owner is entitled to a presumption of nexus when it shows that the asserted objective evidence is tied to a specific product that embodies the claimed features, and is coextensive with them. When nexus is presumed, the burden shifts to the party asserting obviousness. Even absent a presumption of nexus, a party can prove nexus by showing that the secondary consideration evidence is the direct result of the unique characteristics of the claimed invention. Volvo argued that the Board incorrectly found that a presumption of nexus was not met and that Volvo did not otherwise show nexus.

The Federal Circuit agreed with the Board that although the product embodies the invention, Volvo failed to provide sufficient argument on coextensiveness. The Federal Circuit agreed that a single sentence of "Volvo Penta's Forward Drive is a commercial embodiment of the '692 Patent and coextensive with the claims," along with a cite to an expert declaration is insufficient to show a presumption of nexus.

However, the Federal Circuit found that the Board did not sufficiently consider the invention as a whole and the Board's finding of a lack of nexus was not supported by substantial evidence. In particular, the Board did not sufficiently consider that the claimed features are the reason for the commercial success of the Forward Drive system. The Federal Circuit further held the Board did not sufficiently consider its own statement that Brunswick's system was "akin to copying" and was motivated by Volvo's Forward Drive design. Finally, at oral argument, the USPTO argued that to the extent Volvo identified these claims elements as unique characteristics, they already existed in the prior art. However, the Federal Circuit cannot consider that argument, because it was not a basis upon which the Board reached its decision. Based on the Board's considerations, the Board's finding of a lack of nexus is not supported by substantial evidence and instead, the Federal Circuit held that Volvo demonstrated a nexus between the claims and its evidence of secondary consideration.

Objective Indicia of Nonobviousness

The Federal Circuit agreed with Volvo's argument that the Board's analyses of objective indicia of nonobviousness, including its assignment of weights to different considerations, was vague and ambiguous. For example, the Board found there was "some weight" of nonobviousness based on Brunswick's internal documents indicating how the Forward Drive guided Brunswick's design of the Bravo Four S system. The Federal Circuit held the Board's assignment of "only some weight" was not supported by substantial evidence.

Although the Board acknowledged that boat manufacturers strongly desired the Forward Drive system and that manufacturers were urging Brunswick to design its own version of the Forward Drive system, the Board again only afforded "some weight" of nonobviousness based on commercial success. For these considerations along with others, the Board did not explain why the evidence was limited to "some weight" and it also failed to explain whether "some weight" in all cases were the same weight.

The Federal Circuit also highlighted the Board's failure to evaluate the long-felt but unresolved need of the invention and the time between the asserted prior art references and the filing date. The Board's understanding of the cited evidence was not supported by substantial evidence, because, for example, the Board failed to give any explanation as to why it gave very little weight to a magazine article that described the Forward Drive as "radical," "game-changing," and starting a "revolution."

Finally, the Board's ultimate conclusion that evidence of obviousness outweighed evidence of nonobviousness without explanation was an error, especially in light of its error in assessing the weight of the various objective indicia of nonobviousness.

Elekta Limited v. Zap Surgical Systems, Inc.

No. 2021-1985 (Fed. Cir. Sept. 21, 2023)

By: Zachary Alper

Topic

This case addresses the interplay between findings related to motivation to combine and reasonable expectation of success in determining obviousness under 35 U.S.C. § 103.

Background

Elekta Limited ("Elekta") is the owner of U.S. Patent No. 7,295,648 (the "'648 patent), which discloses "a device for treating a patient with ionizing radiation for certain types of radiosurgery and radiation therapy." "The invention uses a radiation source, e.g., a linear accelerator (referred to as a 'linac'), mounted on a pair of concentric rings to deliver a beam of ionizing radiation to the targeted area on the patient."

The instant dispute between Elekta and ZAP Surgical Systems, Inc. ("ZAP") stems from an IPR filed by Zap which challenged claims 1-4, 7-13, 16-18, 20, and 22-23 of the '648 Patent. The Board instituted the IPR on April 1, 2020 and issued its final written decision on March 30, 2021. In the final written decision, the Board found all challenged claims of the '648 patent obvious in light of the combination of U.S. Patent No. 4,649,560 ("Grady") and a publication, K.J. Ruchala et al., *Megavoltage CT image reconstruction during tomotherapy treatments*, Phys. Med. Biol. 45, 3545-3362 (2000) ("Ruchala").

As described by the Federal Circuit, Grady discloses an X-ray tube mounted on a sliding arm connected to a rotating support that allows the arm to be rotated around a patient to take X-ray images. Ruchala discloses a "linac-based tomotherapy treatment system" wherein "'the patient remains still, but the linac and detector rotate about the patient' to deliver a treatment dose to the target tumor."

During the IPR, Elekta argued that a person of ordinary skill in the art would not have been motivated to combine, and would not have had a reasonable expectation of success in combining, the Grady device with the linac described in Ruchala, particularly in light of the fact that the Grady device was an imaging device, rather than a radiation device, and because the weight of the linac in Ruchala would render the Grady device inoperable, imprecise, and unsuitable for treatment. The Board disagreed and found a motivation to combine Grady with Ruchala, rendering the '648 patent invalid due to obviousness. Elekta appealed the Board's final written decision to the Federal Circuit.

Issue(s)

On appeal, Elekta challenged the Board's findings with respect to motivation to combine, arguing that it was not supported by substantial evidence. Elekta also argued that the Board failed to make any findings, either explicitly or implicitly, with respect to reasonable expectation of success, and even if such findings were made, that they were not supported by substantial evidence. Based on Elekta's arguments, the Board considered the following issues:

- Whether there was substantial evidence for the Board to find that a skilled artisan would have been motivated to combine the prior art references disclosing radiation imagery (Grady) with the references disclosing radiation therapy (Ruchala)?
- Whether the Board erred as a matter of law because it failed to articulate any findings on reasonable expectation of success?

- Whether, even if the Board made an implicit finding with respect to reasonable expectation of success, there was substantial evidence to support a finding that a skilled artisan would have reasonably expected to succeed in combining the asserted references?
- Whether the proper burden of proof with respect to reasonable expectation of success is clear and convincing evidence or a preponderance of the evidence?

Holding(s)

- There was substantial evidence to support the Board's finding that a skilled artisan would have been motivated to combine the asserted prior art references.
- In discussing motivation to combine, the Board made sufficient implicit findings to support its conclusion that a skilled artisan would have had a reasonable expectation of success in combining the asserted prior art references.
- There was substantial evidence to support the Board's finding that a skilled artisan would have had a reasonable expectation of success in combining the asserted prior art references.
- The proper burden of proof with respect to reasonable expectation of success is preponderance of the evidence. See 35 U.S.C. § 316(e).

Reasoning

Elekta argued that no substantial evidence existed to support the Board's motivation to combine finding because the linac device in Ruchala would not offer any improvement to the imaging capabilities of Grady and further that the Grady device does not "contemplate a heavy linac or account for the lack of precision that would result from the linac's additional weight." The Federal Circuit disagreed and pointed to the "the prosecution history of the '648 patent, the teachings of the asserted prior art references, and the expert testimony of record" as evidence supporting the Board's finding that a skilled artisan would have been motivated to combine the asserted prior art references.

The Federal Circuit credited the Board's finding that during prosecution "the patentee notably did not argue that prior art references directed to imaging devices were not relevant art." Further, the Federal Circuit noted that the prior art, specifically Ruchala and U.S. Patent No. 4,998,268 ("Winter"), describes the advantage of having a single device capable of imaging and delivering radiation, namely, more accurate radiation delivery. With respect to the weight of the linac, the Federal Circuit references the Board's findings that "heavy linacs were known in the art during the pertinent period and that their weight could be adequately handled by robotic arms." Finally, the Federal Circuit pointed to ZAP's expert, who opined that combining the imaging apparatus with the treatment apparatus would eliminate the need to transfer the patient from one apparatus to the other and would reduce the patient's exposure to radiation.

Based on the above, the Federal Circuit found that substantial evidence existed to support the Board's finding that a person of ordinary skill in the art would have been motivated to combine the imaging device of Grady with the radiation delivery device of Ruchala.

Elekta argued that the Board's decision should be reversed because the Board failed to make any findings with respect to reasonable expectation of success. An obvious determination requires a motivation to combine prior art references and a reasonable expectation of success in doing so. *See Regents of Univ. of California v. Broad Inst., Inc.*, 903 F.3d 1286, 1291 (Fed. Cir. 2018). The Federal Circuit explained that while the motivation to combine determination requires an explicit analysis, a finding of reasonable expectation of success can be implicit where the arguments and evidence on reasonable expectation of success are intertwined with those addressing motivation to combine.

For example, Elekta argued that the proposed prior art combinations would lead to an inferior quality product, an inoperable device, and would teach away because the weight of the linac device would not be supported by the device disclosed in Grady. The Federal Circuit reasoned that Elekta's arguments were addressed to both motivation to combine and reasonable expectation of success, and thus the Board did not err in implicitly addressing reasonable expectation of success by explicitly discussing motivation to combine, particularly where Elekta presented the arguments in a blended manner. On this basis, the Federal Circuit determined that the Board made sufficient implicit findings that a skilled artisan would have had a reasonable expectation of success in combining the prior art references.

Elekta argued that even if the Board made a proper implicit finding on reasonable expectation of success, there was not substantial evidence that could support a finding that a skilled artisan would have reasonably expected to succeed in combining the asserted references. In rejecting Elekta's argument, the Federal Circuit again focused on the intertwined nature of the motivation to combine

arguments and the arguments directed to reasonable expectation of success. While not always the case that a finding of motivation to combine establishes a reasonable expectation of success, where the evidence and arguments overlap, as they do here, the evidence establishing a motivation to combine may establish a finding of reasonable expectation of success.

As such, because the evidence with respect to motivation to combine was sufficient to support the Board's finding on motivation to combine, the same arguments and evidence were sufficient with respect to reasonable expectation of success.

The Federal Circuit quickly dismissed Elekta's argument on the applicable burden of proof by citing 35 U.S.C. § 316(e), which provides that "[i]n an *inter partes* review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence."

Jodi A. Schwendimann, fka Jodi A. Dalvey v. Neenah, Inc., Avery Products Corporation

Nos. 2022-1333, 2022-1334, 2022-1427, 2022-1432 (Fed. Cir. Oct 6, 2023)

By: Evan Lim

Topic

This case addresses whether there was substantial evidence to support that a person of ordinary skill in the art had motivation and a reasonable expectation of success in combining references to render obvious the incorporation of a white pigment of a first reference to the layers of a transfer sheet of a second reference to improve the transfer of images onto dark fabrics.

Background

Schwendimann sued Neenah for patent infringement of U.S. Patent RE41,623 ("the '623 patent"), U.S. Patent 7,749,581 ("the '581 patent"), U.S. Patent 7,754,042 ("the '042 patent"), U.S. Patent 7,766,475 ("the '475 patent," and collectively with the '623 patent, '581 patent, and '042 patent, "the Appealed Patents"), and four other patents.

Neenah filed petitions for *inter partes* review with the U.S. Patent and Trademark Office Patent Trial and Appeal Board (the "Board") for all claims of the '623 patent, '042 patent, and '475 patent, claims 1-6, 8-21, and 24-31 of the '581 patent (collectively the "Challenged Claims"), and claims of one of the other four patents.

The Board found that the Appealed Patents share a specification, and relate to transfer sheets and methods for transferring images onto dark-

colored fabrics by applying a white background to the transfer sheets. The Board also found that the Appealed Patents disclose that multi-layer image transfer sheets for transferring images onto fabrics were well known in the prior art.

Neenah asserted that the claims of these patents were rendered obvious on multiple separate grounds based on different prior art combinations, including based on U.S. Patent 5,798,179 ("Kronzer") in view of U.S. Patent 5,655,476 ("Oez"). Neenah asserted that a skilled artisan would incorporate the white pigment taught in Oez into the transfer sheet of Kronzer. The Board instituted *inter partes* review of all of the Challenged Claims of the Appealed Patents and found them unpatentable as obvious over Kronzer in view of Oez.

The Board addressed Schwendimann's arguments that challenged (i) the combination of Kronzer and Oez, (ii) whether a skilled artisan would have been motivated to combine Kronzer and Oez, and (iii) whether the combination of Kronzer and Oez would have yielded a reasonable expectation of success. The Board disagreed with Schwendimann's arguments and ultimately concluded that Kronzer in view of Oez rendered the Challenged Claims of the Appealed Patents unpatentable as obvious.

Schwendimann appealed the final written decision of the Board of the *inter partes* review of the Challenged Claims of the Appealed Patents.

Issue(s)

- Whether there is substantial evidence to support a finding that (i) a person of ordinary skill in the art would have been motivated to combine Kronzer and Oez, and (ii) such a combination of Kronzer and Oez would have yielded a reasonable expectation of success.

Holding(s)

The Federal Circuit affirmed the Board's finding that the Appealed Patents are unpatentable as obvious over Kronzer in view of Oez.

Reasoning

The Board found that the Appealed Patents all cite Kronzer as prior art. The Board found that Kronzer is directed to "a heat transfer material, such as a heat transfer paper" for use in the "application of customer-selected design, messages, illustrations, and the like … on articles of clothing, such as T-shirts, sweat shirts, and the like." The Board also found that Kronzer disclosed numerous multi-layered image transfer sheets and the use of a "peel-last" application method that includes (1) printing the desired image as a mirror image onto the transfer sheet, (2) applying the transfer sheet to the fabric image-side down, (3) applying heat and pressure to transfer the image onto the fabric, and (4) peeling a base/substrate layer and a release layer of the transfer sheet away to reveal the final product.

The Board found that Oez is also directed to multi-layered image transfer sheets and methods of using the image transfer sheets "for transferring photocopies to textiles, such as, in particular, T-shirts." The Board also found that Oez taught the inclusion of a white pigment in a layer of an image transfer sheet to provide a white background for the image to improve image quality when transferring images onto dark fabrics. The Board further found that Oez disclosed the use of a "peel-first" application method that includes (1) printing the desired image positively (i.e., not as a mirror image), (2) peeling a base/substrate layer and a release layer of the transfer sheet away before transferring the image, (3) applying the transfer sheet to the fabric image-side up, and (4) applying heat and pressure to transfer the image onto the fabric.

In addressing Schwendimann's first argument that a skilled artisan would not have been motivated to combine Kronzer and Oez because their teachings are "diametrically opposed" and "flatly inconsistent," the Federal Circuit found this argument unpersuasive based on the substantial evidence. The Federal Circuit found that the disclosures of Kronzer and Oez, along with the expert testimonies of Schwendimann's expert and Neenah's expert, supported a finding that Kronzer and Oez were complementary and compatible in improving the transfer of images given that Kronzer expressly taught that pigments could be included in a layer of its transfer sheet and Oez expressly taught including a white pigment. Thus, the Federal Circuit found that there was substantial evidence to support the Board's finding that a skilled artisan would have been motivated to combine the Kronzer and Oez.

In addressing Schwendimann's second argument that a skilled artisan would not have had a reasonable expectation of success combining Kronzer and Oez, the Federal Circuit found that there was substantial evidence that made this argument unpersuasive. First, the Federal Circuit found that the disclosure in Oez is substantial evidence to support the Board's finding that Oez does not teach away

from a combination with Kronzer because Oez does not discourage a skilled artisan or lead a skilled artisan away from using a white pigment in the same or similar way as disclosed in the Appealed Patents. Second, the Federal Circuit found that Kronzer's lack of disclosure of failed trials that included transfer sheets with pigments, Neenah's expert's testimony, and other scientific literature in the record were substantial evidence to support the Board's analysis and conclusion that the proposed combination of Kronzer and Oez would not lead to unpredictable results, such as unpredictable chemical reactions. Third, the Federal Circuit found that there was substantial evidence to support the Board's finding that a skilled artisan would understand how to combine Kronzer and Oez by using common sense to adjust the different application methods of Kronzer and Oez to successfully transfer an image using white pigment. Thus, the Federal Circuit found that there was substantial evidence supporting the Board's finding that the proposed combination of Kronzer and Oez would not have led to unpredictable results and a skilled artisan would have had the common sense to make the proposed combination to arrive at the subject matter of the Challenged Claims of the Appealed Patents.

Lastly, in addressing Schwendimann's third argument that Neenah failed and the Board erred in explaining why a skilled artisan would have chosen Kronzer as the primary reference for the proposed combination, the Federal Circuit found that Schwendimann did not have any exceptional circumstances that warrant consideration of this primary reference argument and that Schwendimann ultimately forfeited her ability to raise this argument before the court.

Regardless, the Federal Circuit found that Neenah and the Board adequately explained that the basis for having Kronzer be the primary reference is that adding a white pigment to the layers of Kronzer's transfer sheet would improve the transfer sheets for application to dark fabrics. Ultimately, the Federal Circuit found that there was substantial evidence to clearly support the Board's obviousness conclusion, refuting any concern of hindsight bias.

Corephotonics, Ltd. v. Apple Inc.

Nos. 2022-1340, 2022-1341 (Fed. Cir. Oct. 16, 2023)

By: Li Guo

Topic

This decision addresses the Patent Trial and Appeal Board's ("Board" or "PTAB") obviousness determinations in five final written decisions. Specifically, this decision concerns whether the Board committed procedural and substantive errors in concluding the prior art references at issue are analogous art.

Background

Corephotonics appealed the Board's final written decisions concluding the challenged claims are unpatentable as obvious.

The Challenged Patents relate to dual-aperture camera systems and disclose techniques for using images from both camera lenses when zooming while capturing video. Two prior art references are part of all of the obviousness grounds Apple presented in its IPR petitions: Golan and Martin. Golan describes camera systems using multiple imaging sensors and lens assemblies to zoom without using a lens with a mechanically adjustable focal length. Martin describes methods for producing two-dimensional images that, upon display, can be perceived to be three-dimensional without the use of special viewing aids. The Board found that Golan and Martin are analogous prior art.

In its petitions, Apple said that the Golan and Martin "references are analogous prior art and are in the *same field of endeavor* pertaining to imaging systems generating video output images using two imaging sections having different points of view." Apple did not make clear whether it was stating that Golan and Martin are in the same field of endeavor as the Challenged Patents or, instead, merely that Golan and Martin are in the same field of endeavor as one another, and this ambiguity was present in the Apple's expert declarations.

Moreover, there is no express reference in either Apple's petitions or its expert declarations to the field of endeavor of the Challenged Patents themselves. Nor is there any explicit contention that Golan and Martin are analogous *because* they are pertinent to the problem faced by the inventors of the Challenged Patents. However, Corephotonics did not address these issues in its patent owner preliminary response. In addition , the Board's institution decision did not address the issue of whether Apple had said enough to satisfy its obligation to establish Golan and Martin are analogous art.

After the IPRs were instituted, Corephotonics filed its patent owner response, in which it argued there was a deficiency in how Apple had addressed the analogous art issue at the petition stage. Apple clarified its position in its Replies, explicitly arguing that the Challenged Patents, Golan, and Martin are *all* in the same field of endeavor. Further, Apple's Replies added, for the first time, that the two prior art references were also *pertinent to the problem* faced by the inventors of the Challenged Patents. Corephotonics's Sur-Reply complained that Apple's Replies raised completely new arguments.

The Board addressed the analogous art disputes in the final written decisions. First, the Board agreed with Corephotonics that Apple's treatment of the analogous art issue in its petitions was deficient because Apple and its expert had not explicitly mentioned or discussed the Challenged Patents' field of endeavor. Instead, the Board found Apple improperly compared Golan and Martin to each other instead of the claimed invention. However, the Board found that Apple's Replies rectified this improper comparison and asserted that Golan and Martin are in the same field of endeavor as the claimed invention. The Board further held that Apple properly replied to Corephotonics's criticism of its showing regarding analogous art. The Board also found all Apple's arguments about the analogousness of its prior art were within the scope of a proper reply. On the merits, the Board's analogousness analysis was materially uniform across the four IPRs.

On appeal, Corephotonics argued that the Board committed procedural and substantive errors in concluding Golan and Martin are analogous art.

Issue(s)

- Whether the Board committed procedural and substantive errors in concluding Golan and Martin are analogous art.

Holding(s)

The Federal Circuit identified no procedural error in the Board's analysis of whether Golan and Martin are analogous art. The Court further held that the Board's determination that Golan is analogous art is supported by substantial evidence. However, the Court vacated and remanded the Board's obviousness determination for the Board to explain why Martin is (or is not) analogous art and how this finding affects its overall conclusion as to obviousness.

Reasoning

Relying on *Sanofi-Aventis Deutschland GmbH v. Mylan Pharms. Inc.*, 66 F.4th 1373, 1377 (Fed. Cir. 2023), the Federal Circuit rejected Corephotonics' argument that the Board abused its discretion by permitting Apple to fix the error in its petition because a petitioner is not required to anticipate and raise analogous art arguments in its petition, and by finding instead that a petitioner can use its reply to respond to, for example, arguments raised in a patent owner response.

The Federal Circuit next rejected Corephotonics' argument that the Board erred in permitting Apple to argue in reply that its prior art references are analogous to the Challenged Patent because they satisfy both the field of endeavor and pertinent to the problem tests, even though Apple's petition only invoked the field of endeavor test. In doing so, the Court again relied on *Sanofi-Aventis*, which explained that a petitioner may use its reply to respond to the patent owner response's arguments against the references being analogous. The Court noted that Apple was not required to

anticipate in its petition that Corephotonics would argue Golan and Martin were not in the same field of endeavor as the Challenged Patents. Once Corephotonics did so in its patent owner response, Apple was permitted to respond both by bolstering its field of endeavor argument and by showing that its prior art is pertinent to the problem faced by the inventors of the Challenged Patents.

The Federal Circuit disagreed with Corephotonics that the Board erred by finding analogousness based on a different field of endeavor and different problem of the inventors than those expressly advocated for by Apple. The Court found no procedural error in the Board's approach, and noted that as long as substantial evidence supported its findings, the Board may resolve an issue the parties put in dispute by making findings supported by the evidence, regardless of whether any party advocated for that particularly expressed finding. The Court noted that while the Board may not invalidate patent claims on grounds it identifies *sua sponte* that the petitioner has not actually raised, the Board is not required to use the same words in explaining its findings as the petitioner used in its papers. Therefore, here, too, the Board may make its own finding as to the field of endeavor or problem confronted by the inventors—when those issues are in dispute—even if its finding differs from the parties' positions. The Court noted that the Board did nothing more than resolve the factual disputes underlying obviousness that the parties presented, and the fact that the Board's findings differed slightly from what Apple had proposed, and that its articulation of the field of endeavor and pertinent problem were not identical to Apple's advocacy, do not constitute error. In sum, the Federal Circuit found no procedural error in the Board's handling of the analogous art issue.

Regarding the Board's factual findings, the Federal Circuit found that substantial evidence supported that Golan is in the same field of endeavor as the Challenged Patents. As for Martin, both Apple and Corephotonics agreed that the Board's relevant finding was, as written, incorrect. Apple argued that the Board's statement included a mere "typographical error" and, therefore, was harmless. The Federal Circuit, however, was unable to discern if the Board's error was, in fact, merely typographical and harmless or was instead a potentially-impactful error of substance. The Court therefore remanded for further proceedings and directed the Board to explain why Martin is (or is not) analogous art and how this finding affects its overall conclusion as to obviousness.

FS.COM Inc. v. International Trade Commission Corning Optical Communications LLC

No. 2022-1228 (Fed. Cir. Apr. 20, 2023)

By: Joshua Weisenfeld

Topic

This case addresses the validity of patents asserted against a high-density fiber optic equipment importer in violation of § 337. In particular, this case discusses enablement and claim construction as it relates to interpretation of open ended ranges and plural claim language.

Background

Corning Optical Communications LLC ("Corning") filed a complaint with the International Trade Commission ("ITC") alleging that FS.COM violated § 337 by importing high-density fiber optic equipment into the United States that infringed Corning's patents. The Administrative Law Judge ("ALJ") that heard the case found that FS.COM had induced infringement of the asserted patent claims and rejected FS.COM's invalidity challenges, including arguments that the claims were not enabled. FS.COM petitioned for ITC review, which was granted in part, including on both the enablement issue and on the claim construction of the limitation "a front opening." The ITC affirmed the ALJ's determination that the claims were enabled and that "a front opening" included numerous openings, and as such that FS.COM violated § 337 and issued a general exclusion order prohibiting the importation of infringing high-density fiber optic equipment into the United States and a cease-and-desist order directed to FS.COM. FS.COM appealed the ITC's determination that the claims were enabled and the claim construction of "a front opening."

Issue(s)

- Whether a claim with an express lower limit and an inherent upper limit, as agreed upon by persons of ordinary skill in the art, is enabled.

- Whether the claim language "a front opening" is limited to a single front opening or inherently includes one or more front openings.

Holding(s)

The Federal Circuit held that the ITC's finding that the claim is enabled was supported by substantial evidence. In particular, the Federal Circuit held that the specifications of the patents at issue, as well as expert testimony from a skilled artisan, had shown that there was a technological limit of about 144 connections per U space, and as such, a skilled artisan would have interpreted the claim language to have an inherent upper limit, and was thus enabled.

The Federal Circuit held that the general rule that the terms "a" or "an" in a patent claim mean "one or more" was properly applied and that the patentee had not evinced a clear intent to limit "a" or "an" to "one."

Reasoning

The Federal Circuit addressed the two issues on appeal separately.

The Federal Circuit affirmed the ITC's finding that the claim language included an inherent upper limit. The claim language at issue recites "a fiber optic connection density of at least ninety-eight (98) fiber optic connections per U space" or "a fiber optic connection of at least one hundred forty-four (144) fiber optic connections per U space." FS.COM argued that these open-ended density ranges were not enabled because without an express upper limit. The Federal Circuit concluded that, based on the ITC's opinion, an inherent upper limit of about 144 connections per U space was present as densities substantially above 144 connections per U space were technologically infeasible at the patent's priority date. As such, the Federal Circuit found that an upper limit, as recognized by a person of ordinary skill in the art, was inherently present in the claims, thus enabling the claims.

The Federal Circuit then addressed the claim construction issue. The claim language at issue was "a front opening," which the ITC had concluded was a term that encompassed one or more openings against FS.COM's argument that such term should be limited to a single opening. The Federal Circuit cited the general rule, which states that the terms "a" or "an" in a patent claim mean "one or more" unless the patentee evinces a clear intent to limit "a" or "an" to "one." FS.COM argued that the recitation of "front openings" (plural) in unasserted claim 63 evinces the patentee's clear intent to limit "a front opening" in the asserted claim. However, the Federal Circuit did not find this argument persuasive as the specification and patent figures clearly disclosed embodiments with one or more front openings. As such, the Federal Circuit found that the claim language "a front opening" did not deviate from the general rule as to not encompass one or more openings.

In Re: Float'N'Grill LLC

No. 2022-1438 (Fed Cir. July 12, 2023)

By: Theo Mayer

Topic

This case addresses the original patent requirement under 35 U.S.C. § 251 that reissue claims must be directed to the invention disclosed in the original patent.

Background

Float'N'Grill LLC ("FNG") filed for reissue of its US Patent No. 9,771,132 ("the '132 patent") to expand the scope of its claim coverage.

The '132 patent is directed to a floating apparatus that supports a grill in a body of water (e.g., a pool). Accordingly, a user can grill while in the body of water.

The specification of the '132 patent describes a floating apparatus that includes a float and a pair of grill supports. Each of the grill supports includes magnets for removably securing a grill to the grill supports. Magnets are the only structure disclosed for removably securing the grill to the grill supports.

As originally issued, claim 1 recited "a plurality of magnets" that exactly mirrored its description in the specification. Claim 1 was allowed in the first Office Action without rejection.

During prosecution of the reissue application, certain claims were rejected for failure to satisfy the original patent requirement of 35 U.S.C. § 251 because the rejected claims did not include the "plurality of magnets" limitation present in the original patent. Namely, the Examiner found the '132 patent disclosed "a single embodiment of a floating apparatus for supporting a grill" that required a "plurality of magnets" for securing a grill to the grill supports. In other words, the magnets were not an "optional feature."

The Patent Trial and Appeal Board ("the Board") sustained a majority of the Examiner's rejections. FNG appealed.

Issue(s)

- Do FNG's rejected reissue claims which exclude the "plurality of magnets" limitation satisfy the original patent requirement of 35 U.S.C. § 251?

Holding(s)

FNG's rejected reissue claims which exclude the "plurality of magnets" limitation do not satisfy the original patent requirement of 35 U.S.C. § 251 because the reissue claims broadened a limitation to cover undisclosed alternatives to a feature appearing from the face of the original specification to be a necessary, critical, or essential part of the invention.

Reasoning

A patentee seeking to change claim scope through reissue is subject to additional statutory limitations in 35 US.C. § 251. Namely, the reissue claims must be directed to "the invention disclosed in the original patent." This is known as the "original patent" requirement of § 251.

The Supreme Court provided the black-letter law for the original patent requirement in *U.S. Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals, Corp.*, 315 U.S. 668 (1942). In that case, the Supreme Court found the relevant inquiry is "whether, in the light of the disclosures contained in the [original patent and the reissue], they are for the same invention." The Supreme Court concluded that the original patent and the reissue are for the same invention "if the reissue fully describes and claims the very invention intended to be secured by the original patent." The Supreme Court also found that a claim of the reissue is invalid as directed to a different invention if that claim omits a step that the original patent "described and claimed as an integral part of the whole operation."

Applying the principles from *U.S. Industrial Chemicals*, the Federal Circuit agreed with the Board that the reissue claims in this case were not directed to the invention disclosed in the original patent and, therefore did not meet the original patent requirement of § 251.

To support this finding, the Federal Circuit reasoned:

- the magnets are not described as optional, representative of removable fasteners generally, or exemplary of a broader invention;
- the magnets are an essential part of the invention as they are the only disclosed structure for performing the necessary task of removably and safely securing the grill to the floating apparatus;
- the specification contains nothing to suggest to one of ordinary skill in the art that alternative mechanisms may be used in place of the magnets or that the magnets act as a stand-in for a broader category of removable fasteners; and
- the magnets are described in definitional and necessary terms in the original specification.

Baxalta Incorporated v. Genentech, Inc.

No. 2022-1461 (Fed. Cir. Sept. 20, 2023)
§ 112(a) Enablement

By: Theo Mayer

Topic

This case addresses the enablement requirement in view of the Supreme Court's recent decision in *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023).

Background

Baxalta Inc. and Baxalta GmbH (collectively "Baxalta") sued Genentech Inc. ("Genentech") for infringement of US Pat. No. 7,033,590 ("the '590 patent").

The asserted claims of the '590 patent are drawn to antibodies (or antibody derivatives) for treating Hemophilia. Representative of the asserted claims, independent claim 1 of the '590 patent recites "[a]n isolated antibody or antibody fragment thereof that binds Factor IX or Factor IXa and increases the procoagulant activity of Factor IXa."

On remand, the district court granted summary judgement for Genentech based on a finding that the asserted claims of the '590 patent were invalid for lack of enablement. Baxalta appealed.

Issue(s)

- Did the specification of the '590 patent enable the "full scope" of the claimed antibodies without undue experimentation?

Holding(s)

The specification of the '590 patent did not enable the "full scope" of the claimed antibodies without undue experimentation because: (1) "[t]here are *millions* of potential candidate antibodies [covered by the asserted claims] … but the written description discloses the amino acid sequences for only *eleven* antibodies with the two claimed functions;" and (2) any roadmap contained in the specification of the '590 patent to make or use undisclosed antibodies "simply directs skilled artisans to engage in the same iterative, trial-and-error process the inventors followed to discover the eleven antibodies they elected to disclose" – which the Supreme Court previously held to be insufficient to satisfy the enablement requirement in *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023).

Reasoning

The Federal Circuit based its enablement analysis on the recent Supreme Court decision in *Amgen*.

In *Amgen*, the asserted patents claimed all antibodies that (1) bind to specific amino acid residues on a protein known as PCSK9; and (2) block PCSK9 from binding to LDL receptors. The Federal Circuit noted that similar to the '590 patent, "[t]he full scope of the claims [in *Amgen*] covered potentially millions of antibodies, but the specification only disclosed the amino acid sequences of twenty-six antibodies that performed the two claimed functions." The specification in *Amgen* included a "roadmap" that skilled artisans could follow to make and use undisclosed antibodies. The specification in *Amgen* also indicated that skilled artisans could employ a technique known as "conservative substitution" to make and use undisclosed antibodies.

The Supreme Court held that Amgen's roadmap and the disclosed conservative substitution methods "amount[ed] to little more than two research assignments" and failed to enable the full scope of the claims. *Amgen*, at 612–15. Namely, the Supreme Court reasoned that Amgen's roadmap "merely describes step-by-step Amgen's own trial-and-error method for finding functional antibodies—calling on scientists to create a wide range of candidate antibodies and then screen each to see" which practice the claims. *Id*. at 614. Relatedly, the Supreme Court found the conservative substitution method simply "requires scientists to make substitutions to the amino acid sequences of antibodies known to work and then test the resulting antibodies to see if they do too—an uncertain prospect given the state of the art." *Id*.

The Federal Circuit found the facts from this case "materially indistinguishable from those in *Amgen*." Namely, the Federal Circuit found that "[j]ust like the roadmap rejected by the Supreme Court in Amgen, the '590 patent's roadmap simply directs skilled artisans to engage in the same iterative, trial-and-error process the inventors followed to discover the eleven antibodies they elected to disclose."

Addressing the Supreme Court's suggestion in *Amgen* that methods like a roadmap or conservative substitution *might* be sufficient for enablement where a patent discloses "a quality common to every functional embodiment" – the Federal Circuit further noted that the '590 patent included no such disclosures "that would allow a skilled artisan to

predict which antibodies will perform the claimed functions." Instead, the Federal Circuit found that "[t]he only guidance the patent provides is 'to create a wide range of candidate antibodies and then screen each to see which happen to bind' to Factor IX/IXa and increase procoagulant activity." (citing *Amgen*, at 614).

Addressing one of Baxalta's attempts to distinguish from *Amgen*, the Federal circuit further stated that "[e]ven accepting as true that skilled artisans will generate at least one claimed antibody each time they follow the disclosed process, this does not take the process out of the realm of the trial-and-error approaches rejected in *Amgen*. *Amgen* made clear that § 112(a) requires inventors to enable the 'full scope' of the claimed invention without unreasonable experimentation… Here, it is undisputed that to practice the full scope of the claimed invention, skilled artisans must make candidate antibodies and screen them to determine which ones perform the claimed functions… **This is the definition of trial and error and leaves the public no better equipped to make and use the claimed antibodies than the inventors were when they set out to discover the antibodies over which they now have an exclusive right."** (emphasis added) (citing *Amgen* at 610-612).

Sisvel International S.A. v. Sierra Wireless, Inc.

Nos. 2022-1493, 2022-1547 (Fed. Cir. Oct. 6, 2023)

By: James Hurt

Topic

This case addresses whether identifying protocols by name may disclose sufficient structure for computer-implemented means-plus-function limitations.

Background

Sierra Wireless challenged claims 1-10 of Sisvel's U.S. Patent No. 6,529,561 ("the '561 patent") in an *inter partes* review. The Patent Trial and Appeal Board's final written decision found claims 1-3 and 9 unpatentable, but upheld the patentability of claims 4-8 and 10.

The '561 patent relates to wireless channel coding, which inserts redundant information into the digital data in a structured manner to combat noise and interference during radio transmission. Specifically, the '561 patent uses link adaptation (changing the amount of redundancy inserted dynamically) and incremental redundancy (retransmission of blocks received in error, potentially with a different puncturing pattern).

The Board found that the Chen reference rendered obvious claims 1-3 and 9. The Board also found that claim 5 and 10 recited a means-plus-function claim limitation for "means for detecting" that the specification failed to disclose sufficient structure for and therefore the Board did not evaluate the unpatentability of claims 5-7, and 10, because it was "unable to conclude what structure is encompassed" by the "means for detecting" limitation. Furthermore, the Board found that Sierra's expert testimony could not remedy the lack of sufficient structure disclosed in the specification.

The Board also found that Sierra's motivation to combine Chen with certain GSM references was insufficient.

The parties cross-appealed the adverse findings against them.

Issues

The Federal Circuit considered several issues on appeal:

- Whether substantial evidence supports unpatentability based on Chen.
- Whether substantial evidence supports the Board's finding of a lack of motivation to combine Chen with the GSM references.
- Whether the Board erred in failing to consider expert testimony with respect to whether a protocol name sufficient discloses an understood algorithm to a skilled artisan.

Holdings and Reasoning

Substantial evidence supported the Board's unpatentability findings based on Chen.

Sisvel made two primary arguments. The Federal Circuit found both arguments unavailing. First, Sisvel argued that Chen failed to disclose a second puncturing pattern. The Federal Circuit disagreed and found that Chen disclosed an original transmission and a retransmission, with the transmissions using different code symbols from the output of the convolutional encoder. Sierra's expert witness, Dr. Paul Kakaes, explained that "Chen's selective transmission of selected code symbols from certain generators to refer to puncturing, such that the original transmission with only code symbols from generators g0 and g1 correspond to a 'first puncturing pattern' and the retransmitted packet with additional code symbols (e.g., g2) corresponds to a 'second puncturing pattern.'"

Second, Sisvel argued that Chen failed to disclose the "combining" limitation and that Chen's interleaving is different than the required "combining" limitation. The Federal Circuit disagreed again, and found that "combining as recited in claim 1" does not "exclude[] interleaving as taught by Chen." In addition, despite Sisvel's argument that Chen includes a statement that "retransmitted packets are interleaved (not combined), other teachings of Chen taught accumulating and combining packets.

Substantial evidence supported the Board's finding of no motivation to combine.

The Federal circuit agreed with the Board and found that Sierra's proposed combinations and rationales were "expressed at such a non-specific, high level of generality, they never made clear to the Board what portions of the references were being combined and why a skilled artisan would identify those particular elements for a combination." Sierra's rationales were found to be assertions that the references were analogous art without more to support motivation to combine, or too conclusory, lacking clarity, or both. The Federal Circuit noted that "[u]nder the circumstances, we cannot fault the Board for being at a loss in trying to decipher [Sierra's] kitchen-sink of unclear and confusing motivation-to-combine arguments.

The Board erred in failing to consider expert testimony under *Noah* because the specification disclosed some algorithm and the sufficiency of adequate structure disclosed in the specification must be evaluated from the perspective of a skilled artisan.

Under *Noah*, for a means-plus-function claim, the case law regarding special purpose computer-implemented means-plus-function claims is divided into two cases: (i) cases where the specification discloses no algorithm and (ii) cases in which the specification discloses an algorithm but a party contends that the disclosure is inadequate.

In the first case where no algorithm is disclosed, the knowledge of skilled artisan is irrelevant. However, in the second case, the sufficiency of the disclosed structure must be evaluated in "light of the knowledge possessed by a skilled artisan."

Here, Sierra relied on software protocols named in the specification, such as ARQ (automatic repeat request) and hybrid FEC/ARQ (forward error correction / automatic repeat request) as examples of structure – and it was not disputed that these protocols were well-understood and well-known to skilled artisans. The Federal Circuit agreed with Sierra that "the Board should have evaluated the protocols discussed in the specification in light of the knowledge of a skilled artisan and conducted an analysis appropriate to *Noah* group two." The Board appeared to classify the case in *Noah* group one and completely disregarded Sierra's expert witness testimony. Here, the Federal Circuit indicated that "for a means-plus-function limitation where the corresponding structure is an algorithm, the specification need not disclose all the details of the algorithm to satisfy the definiteness requirement of § 112 ¶ 2 so long as what is disclosed would be sufficiently definite to a skilled artisan."

The Federal Circuit vacated and remanded for the Board to consider the expert testimony and specifically noted that its opinion does "not reach the merits of the factual question of whether the protocols identified in the '561 patent's specification disclose sufficient structure to satisfy § 112 ¶ 2" and left for the Board to answer that question under the proper *Noah* analysis because "the specification's explicit reference to protocol names—which no party disputes refers to protocols known in the art—is sufficient to bring this case into *Noah* group two."

Grace Instrument Indus., LLC v. Chandler Instruments Co.

No. 2021-2370 (Fed. Cir. Jan. 12, 2023)
§ 112 – Claim Construction and Indefiniteness

By: Roy Jung

Topic

This case addresses (i) whether a term of degree may be indefinite when a patent-at-issue discloses a particular purpose but does not disclose objective dimensional boundaries, and (ii) whether a certain means-plus-function claim was construed correctly.

Background

This is an appeal of a claim construction order. The district court found that the term "enlarged chamber" is a term of degree, which necessarily calls for some comparison against some baseline. Further, the district court concluded that the patent-at-issue does not provide the requisite objective boundaries because a POSITA cannot determine certain dimension to be considered "enlarged." Accordingly, the district court found the term "enlarged chamber" indefinite.

Second, the district court construed "means for driving said rotor to rotate located in at least one bottom section" as (i) function: driving said motor to rotate, where the means for driving is located in at least one bottom section, (ii) means: magnetic coupling (magnetic mount, gear box or motor, driving magnet, coupling magnet), or direct drive at bottom of cell body, and known equivalents.

Issue(s)

1. Whether a term of degree ("enlarged chamber") may be indefinite when a patent-at-issue discloses a particular purpose but does not disclose objective dimensional boundaries.
2. Whether the lower court correctly construed the term "means for driving said rotor to rotate located in at least one bottom section."
   - Whether the term "located in at least one bottom section" modifies "rotor" or "means for driving."
   - Whether the term "bottom section" refers to (i) the bottom section of the pressure vessel located within the viscometer, or (ii) the bottom section of the viscometer."
   - Whether appellant's proposed alternate construction has merit.

Standard of Review

The Court reviews claim construction based on intrinsic evidence de novo and review findings of fact regarding extrinsic evidence for clear error. The ultimate conclusion of indefiniteness is reviewed de novo.

Holding(s)

1. "Enlarged chamber" may be definite but remanded for further fact finding as the term may still be indefinite based on other disclosures.
   - A term of degree may be definite when a POSITA would understand dimensional boundaries in view of a described particular purpose. Further, lack of explicit definition of a term of degree does not mean the term is indefinite.

2. The district court's construction of the term "means for driving said rotor to rotate located in at least one bottom section" is affirmed.

   - The term "located in at least one bottom section" modifies "means for driving."
   - The term "bottom section" refers to the bottom section of the viscometer.
   - The proposed alternate construction cannot be adopted because it lacks support from the specification of the patent-at-issue.

Reasoning

"Enlarged chamber" may be definite because:

- Although the patent-at-issue does not provide an explicit definition of the term "enlarged chamber," the term may still be definite. As *Phillips* explained, a "claim term may be clearly redefined without an explicit statement of redefinition," and "[e]ven when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents."
- A POSITA would have understood the inherent parameters of the "enlarged chamber" through the intrinsic record. In context of the patent-at-issue, "the term 'enlarged chamber' does not require that chamber be larger than some baseline dimensional object; rather it must be large enough to accomplish a particular function."
  - The patent-at-issue discloses the enlarged chamber has to be "large enough to prevent pressurization fluid from entering the lower section of the pressure vessel—where the viscosity of the test sample is being measured—during elevated pressurization." "In other words, the enlarged chamber has to be able to contain enough sample at the pre-pressurization stage such that, during pressurization, the sample fluid level does not fall below the bottom of the enlarged chamber and into the viscometer's lower, testing section."
  - A POSITA "would understand from these disclosures that the 'enlarged chamber' comprises chambers . . . is large enough to prevent the pressurization fluid from mixing with the sample fluid in the lower measurement zone during elevated pressurization, thus avoiding measurement errors caused by commingling of the sample and pressurization fluids in prior-art viscometers."
  - The patent-at-issue and prosecution history further supports this understanding. A POSITA would understand "enlarged chamber" is to prevent commingling of the sample and pressurization fluids in the lower measurement zone without using a seal, thereby avoiding the measurement errors seen in prior-art viscometers like the prior art reference.
  - In other words, like *Nautilus*, a POSITA would have understood the inherent parameters of the "enlarged chamber" through the intrinsic record because it must be a certain minimum size, or large enough, to maintain sample fluid within the enlarged chamber when the sample fluid is under elevated pressurization.
- Further, the Court remanded for further fact finding. The Court reasoned "enlarged chamber" may still be indefinite on other grounds. For example, the claims recite additional limitation that relies on the "density difference" between the fluids—not the enlarged chamber—to prevent mixing.

The district court's construction of the term "means for driving said rotor to rotate located in at least one bottom section" is affirmed.

- The district court's construction is the most natural reading of the limitation. The phrase "located in at least one bottom section" modifies "means for driving," not "rotor." If the patentee intended to colorize "rotor," the phrase "located in at least one bottom section" should have been placed before "to rotate."
- The term "bottom section" refers to the bottom section of the viscometer. Dependent claim 14 requires "means for driving" to operate across the pressure wall, thus, "means for driving" must be located inside and outside the pressure vessel. In other words, it cannot be at the bottom section of a pressure vessel. Further, other limitations and the specification further supports this interpretation.

SSI Technologies, LLC v. Dongguan Zhengyang Electronic Mechanical Ltd.

No. 2021-2345 (Fed. Cir. Feb. 13, 2023)

§ 112 – Claim Construction

By: Zach Alper

Topic

This case addresses whether the district court properly considered discussion in the asserted patent's specification as limiting when construing the claims, as well as whether the plaintiff waived a doctrine of equivalents infringement argument, even though the plaintiff included a limited discussion of the argument in its summary judgment briefing.

Background

SSI Technologies, LLC ("SSI") brought suit against Dongguan Zhengyang Electronics Mechanical LTD ("DZEM") alleging infringement of two of SSI's patents. DZEM counterclaimed in response, alleging invalidity of the two asserted patents and tortious interference with prospective business relations. The patents at issue are generally directed to sensors for determining the characteristics of fluid in a container, such as a fuel tank.

SSI alleged that DZEM's sensors infringe U.S. Patent No. 8,733,153, specifically the '153 patent's determination of whether a contaminant exists in the fluid. The district court construed this limitation to require that the contaminant determination actually consider the measured volume of fluid in the container. Based on the district court's construction and the parties' agreement that DZEM's accused sensor does not consider the measured volume of fluid, the district court granted summary judgment of non-infringement for DZEM. The district court also found that SSI forfeited its doctrine of equivalents arguments.

SSI further alleged that DZEM's sensors infringe U.S. Patent No. 9,535,038, specifically the '038 patent's recitation of a filter that "blocks, or inhibits, air bubbles from entering a sensing area of the fluid sensor." The district court construed "filter" to mean "a porous structure defining openings, and configured to remove impurities larger than said openings from a liquid or gas passing through the structure." Although DZEM's accused product had a rubber cover with four holes, the district court granted summary judgment of non-infringement for DZEM because the four holes did not qualify as "porous," and thus the rubber cover was not a "filter."

In light of the non-infringement rulings and the corresponding absence of risk of future prosecution under the patents-in-suit, the district court dismissed DZEM's invalidity counterclaims without prejudice. The district court also granted summary judgment to SSI on the tortious interference counterclaim under the *Noerr-Pennington* doctrine – which "prohibits suits

based on a defendant's petition to the government for redress of grievances" – as well as the lack of evidence demonstrating that DZEM had any prospective contracts with the companies that SSI was in contact with.

Issue(s)

- Did the district court err in construing claim 1 of the '153 patent to require that the contaminant determination take into account the measured volume of the fluid?
- Did the district court err in construing the term "filter" in claim 9 of the '038 patent?
- Did the district court err in concluding that SSI waived its doctrine of equivalents argument?
- Did the district court err in granting summary judgment in favor of SSI on DZEM's tortious interference counterclaim?
- Did the district court err in dismissing DZEM's invalidity counterclaims?

Holding(s)

- No – The district court was correct to construe claim 1 of the '153 patent to require that the contaminant determination take into account the measured volume of the fluid. Summary judgement of non-infringement affirmed.
- Yes – The district court erred in construing the term "filter," specifically in its application and analysis of its construction. Vacating summary judgment of non-infringement and remand for further proceedings.
- Yes – The district court erred in concluding that SSI waived its doctrine of equivalents argument.
- No – The district court was correct to grant summary judgment to SSI on the tortious interference counterclaim.
- As to the '038 patent, yes, the district court abused its discretion to dismiss the invalidity claim, but as to the '153 patent, no, the district court permissibly exercised its discretion in dismissing the invalidity counterclaims in light of the absence of any apparent risk of future actions against DZEM.

Reasoning

The specification, prosecution history, and words of the claim support the district court's construction:

- The specification describes an error detection method, namely "whether the system detects the DEF being diluted at the same time that the level of the fluid is decreasing." This error detection method corresponds to amendments made in claim 1 in which "a dilution of the fluid is detected while the measured volume of the fluid decreases," as well as a parallel limitation in dependent claim 31. Thus, the district court's construction that requires the contaminant determination to take into account the measured volume of fluid is in line with the evidence.
- The use of the term "measured volume" in claim 1 supports the district court's construction because SSI's alternative proposal, that claim 1 only requires the volume of liquid in the tank to be decreasing, would render the use of the word "measured" superfluous.

In arriving at its conclusion that summary judgment on non-infringement was appropriate, the district court relied on the fact that DZEM's filter uses relatively large holes to deflect bubbles and then vent smaller bubbles from the side, such that DZEM's sensor "does not have a filter that excludes bubbles by straining fluid through a porous surface," as per the district court's construction of "filter."

- The Federal Circuit reversed and remanded this decision because the specification is not limited to a filter with small holes. In fact, the references to filter in the specification are broad and "the scope of a claim is not ordinarily limited to preferred embodiments or a specific example in the specification. Given that the specification makes clear that the filter is not required to screen all bubbles from the sensing area, but only to "reduce the quantity of gas bubbles within a sensing area," the size of the holes of the filter do not necessarily matter, and SSI's construction – "filter" means "a device containing openings through which liquid is passed that blocks and separates out matter, such as air bubbles" – is proper. As such, the district court's summary judgment ruling is vacated and case remanded for further proceedings in line with this opinion.

The district court concluded that SSI failed to develop its doctrine of equivalents arguments. The Federal Circuit reversed and remanded because SSI's summary judgment brief contained a two-page argument on the doctrine of equivalents, and cited to a portion of SSI's expert's report, which set forth the function, way, and result of the operation of DZEM's accused products. Although relatively limited, the above was sufficient to preserve the doctrine of equivalents argument.

DZEM argued on appeal that SSI's communications [letters sent to customers regarding DZEM's alleged infringement] are not protected by the *Noerr-Pennington* doctrine, and even if they are, the communications fall into the "sham litigation" exception to the doctrine. The Federal Circuit found no error in the district court's reasoning that the communications were protected under the *Noerr-Pennington* doctrine because counter to DZEM's assertions, SSI can in fact obtain government action against the foreign entities to which it sent letters. Additionally, the Federal Circuit found that the sham litigation exception did not apply because, as evidenced in SSI's expert report, the suit was not objectively baseless. Thus, the district court's grant of summary judgment to SSI on the tortious interference counterclaim is affirmed.

The Federal Circuit's reasoning here revolves around Article III standing in declaratory judgment actions, where generally a finding on non-infringement does not moot a claim of invalidity such that there is no Article III case or controversy, but a district court has discretion to dismiss an invalidity counterclaim without prejudice where there is a corresponding finding of non-infringement. Thus, the district court did not abuse their discretion to dismiss the invalidity counterclaim for the '153 patent, but because the Federal Circuit reversed the summary judgment of non-infringement finding for the '038 patent, dismissal of the invalidity counterclaim as to the '038 patent should be reversed.

Alterwan, Inc. v. Amazon.com, Inc.

No. 2022-1349 (Fed. Cir. Mar. 13, 2023)
§ 112 – Claim Construction

By: James Hurt

Topic

This case addresses whether stipulations based on a claim construction are defective when the stipulation fails to provide sufficient details to resolve the claim construction disputes.

Background

AlterWAN sued Amazon for infringement of two related patents. The patents were directed to a "private tunnel" that provides "preplanned high bandwidth, low hop-count routing paths between pairs of customer sites." The parties disputed the proper construction of the claim terms "non-blocking bandwidth" and "cooperating service provider."

Amazon proposed a construction for "non-blocking bandwidth" to be "bandwidth that will always be available and will always be sufficient," that mirrored the language of the specification, requiring the bandwidth to always be available even if the Internet is "down." The district court agreed with Amazon.

AlterWAN proposed that no construction was necessary for "cooperating service provider," or, alternatively that it be construed as a "service provider whose transmission equipment is coupled to the path" or "third party service provider whose transmission equipment is coupled to the path." Amazon proposed that the term should be construed as "service provider that agrees to provide non-blocking bandwidth." After the hearing, the district court agreed with Amazon.

The parties stipulated to non-infringement under the court's constructions of "cooperating service provider" and "nonblocking bandwidth." On appeal, AlterWAN challenged the district court's construction of "cooperating service provider" and "nonblocking bandwidth" as well as a third term, "routing." AlterWAN conceded that "routing," was not included in the stipulation, but argued the "routing" be addressed to conserve judicial resources.

Issues(s)

- What is the appropriate appellate action when a stipulation derived from a district court proceeding fail to provide sufficient detail to resolve a claim construction issue presented on appeal?

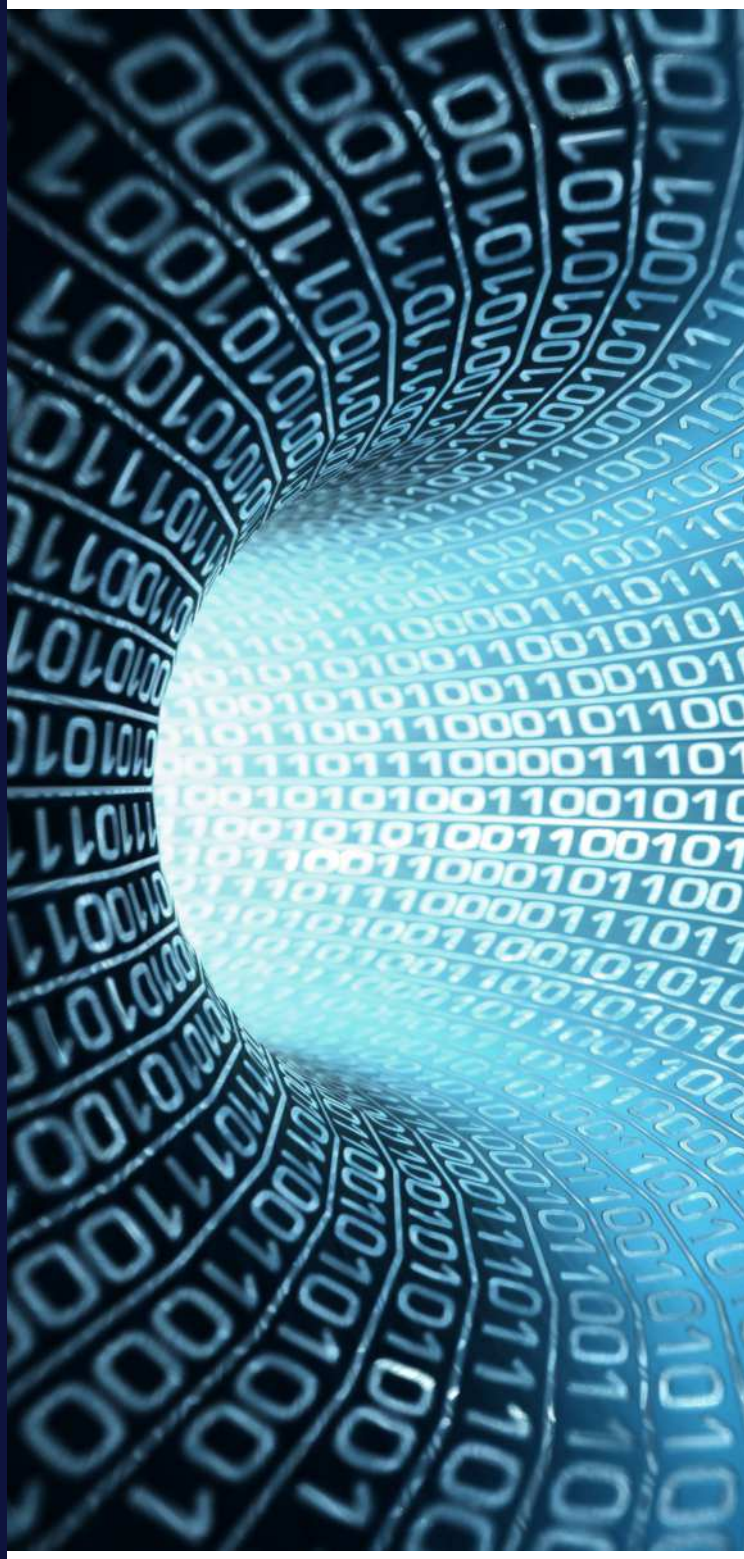
Holding(s)

The Federal Circuit found that "under the circumstances of this case, the stipulation does not provide sufficient detail to allow us to resolve the claim construction issues presented on appeal." "First, the stipulation does not identify which claims of the '471 patent remain at issue in this appeal." "More importantly, it is unclear whether the judgment requires the affirmance of both 'cooperating service provider' and 'non-blocking bandwidth,' where the interpretation of cooperating service provider includes the term 'non-blocking bandwidth.'"

Reasoning

In *Jang v. Bos. Sci. Corp.*, the Federal Circuit "warned of the dangers of stipulating to non-infringement based on a district court's claim constructions without indicating the exact basis for non-infringement." For example, in *Jang*, the parties had entered into a stipulation that suffered two ambiguities. First, the stipulation did not identify which of the district court's claim constructions actually affected the issue of infringement. Second, the stipulation did not provide any factual context as to "how the disputed claim construction rulings relate to the accused products." In *Jang*, the Federal Circuit vacated and remanded, holding that "[a] judgment is reviewable only if it is possible for the appellate court to ascertain the basis for the judgment challenged on appeal."

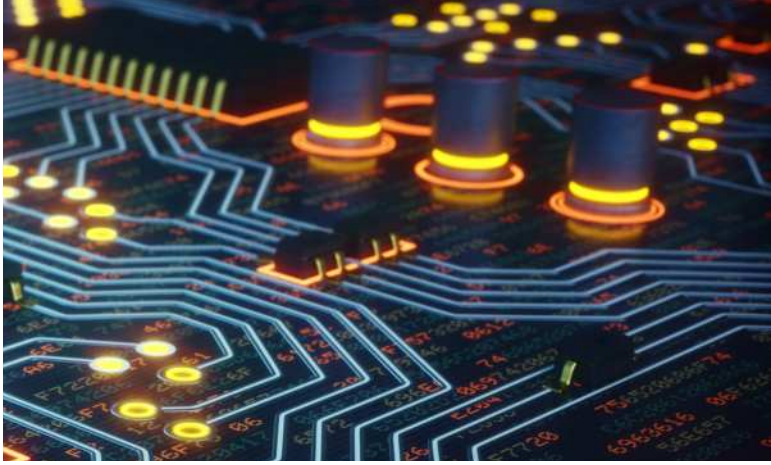
Here, as in *Jang*, the Federal Circuit noted that we cannot "ascertain the basis for the judgment" of non-infringement, because the parties did not adequately explain how the claim construction rulings related to the accused systems. Accordingly, because the stipulation is ambiguous and therefore defective, the Fed. Circuit vacated the judgment and remanded to the district court for further proceedings to clarify the parties' non-infringement positions, and to determine whether a stipulation of non-infringement is even possible in the circumstances of this case.



Salazar v. AT&T Mobility LLC

No. 2021-2320 (Fed. Cir. Apr. 5, 2023)

By: Zachary Alper



Topic

This case addresses the construction of the articles "a" and "said" in relation to subsequently recited functions and whether "a" can be restricted to be singular in its meaning.

Background

Mr. Salazar appealed from the district court's claim construction and subsequent finding of non-infringement. AT&T cross-appealed on the issue of validity. The claim construction dispute centered around the terms "a microprocessor" and "said microprocessor" capable of "creating," "retrieving" and "generating." The district court construed the terms to mean "one or more microprocessors, at least one of which is configured to perform the generating, creating, [and] retrieving [] functions." After trial, AT&T filed for JML on the issues of infringement, damages, and preclusion. The jury found no infringement and that the patent was valid and the district court entered the jury's verdict.

Issue(s)

- Whether the District Court erred in applying principles of claim construction to the terms "a microprocessor" and "said microprocessor".

Holding(s)

The District Court correctly construed the terms "a microprocessor" and "said microprocessor" to mean "one or more microprocessors, at least one of which is configured to perform the generating, creating, retrieving, and generating functions."

Reasoning

The definite article "a" generally "means 'one or more' in open ended claims containing the transitional phrase 'comprising.'" In addition, "use of the term 'said' indicates that this portion of the claim limitation is a reference back to the previously claimed term. Additionally, the use of "said" to refer back to the same claim term adopts the grammatical number (plural or singular) of the original claim term.

The Federal Circuit reasoned based on prior precedent that claim construction of this type must take into consideration subsequent references to the initial noun in order to determine whether the claim requires one item performing all recited functions or any one of multiple items performing any one of multiple functions as long as all functions are performed. For example, in *Varma*, the court reasoned that "a statistical analysis request corresponding to two or more selected investments" is "claim language that introduces a claim element using an indefinite article and further defines the element with subsequently recited functionality, a structure that effectively requires the element be capable of performing all the recited functionality." *In re Varma*, 816 F.3d 1352, 1362-63 (Fed. Cir. 2016). The Court noted in *Varma*, "[f]or a dog owner to have 'a dog that rolls over and fetches sticks,' it does not suffice that he have two dogs, each able to perform just one of the tasks." 816 F.3d at 1363. Thus, a microprocessor, where said microprocessor is capable of performing certain functions, unless otherwise indicated by the specification, claims, or prosecution history, means one or more microprocessors, at least one of which can perform all recited functions.

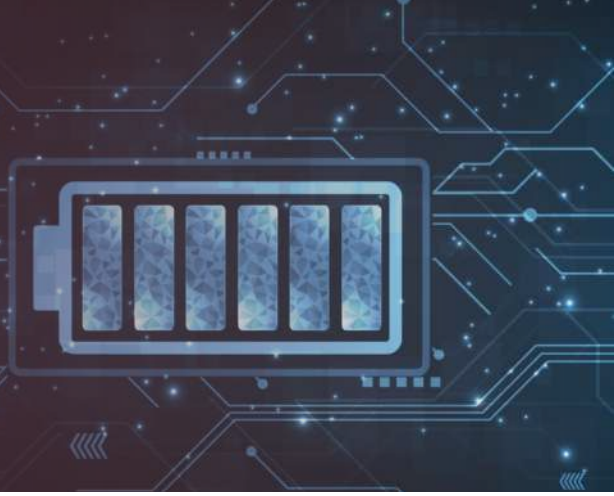
Axonics, Inc. v. Medtronic, Inc.

Nos. 2022-1532, 2022-1533 (Fed. Cir. Aug. 7, 2023)

By: Don Geiger

Topic

This case addresses the ability of a petitioner in an IPR to present new evidence in a reply brief, particularly where the patent owner proposes a new claim construction in its patent owner response.



Background

Medtronic, Inc. ("Medtronic") owns multiple patents relating to transcutaneous (i.e. through the skin) charging of implanted medical devices. These patents seek to improve the efficiency of such transcutaneous chargers by varying output power with current passing through the implanted device.

Axonics, Inc. ("Axonics") filed IPR petitions challenging claims in Medtronic's patents. The parties agreed that one claim from one of the petitions was representative. This representative claim includes the following two clauses (emphasis added):

1. wherein said external power source automatically varies its power output **based on a value associated with said current** passing through said internal power source;

2. wherein said external power source automatically varies its power output **based on a measured current associated with said current** passing through said internal power source.

Axonics did not explicitly propose an express construction of any term in the petition comprising the representative claim, but adopted a "one-input" construction in the claim charts it submitted with the petition. Under the **one-input construction**, the first clause's "value associated with said current" is simply narrowed by the second clause's "measured current associated with said current." Notably, the one-input construction would be satisfied by a prior art embodiment showing only one input value.

Medtronic addressed Axonics' one-input construction in its preliminary patent owner response, taking the position that, even under the one-input construction, the prior art cited by Axonics did not disclose the clauses at issue.

The PTAB rejected Medtronic's position and granted institution under the one-input construction. The PTAB also noted Medtronic's acquiescence to Axonics' framing.

After the institution decision, Medtronic filed its patent owner response, this time arguing validity under a "two-input" construction. Under the **two-input construction**, the first clause's "value associated with said current" and the second clause's "measured current associated with said current" refer to separate measurements. In effect, the two-input construction requires a prior art embodiment to show two separate input values, one input for the "value" clause, and a second input for the "measured current" clause.

In reply, Axonics' submitted arguments, supplemental expert declarations, and citations to show that the previously cited prior art embodiments also disclosed the clauses at issue under the two-input construction.

The PTAB issued a final written decision adopting the two-input construction and refusing to consider Axonic's reply arguments and evidence under the two-input construction because Axionics did not include them in the original petition.

Axonics appealed the PTAB's refusal to consider Axonics' reply arguments and evidence under the two-input construction to the Federal Circuit.

Issue(s)

- Did the PTAB err in refusing to consider Axonics' reply arguments and evidence under the two-input construction, where the two-input construction was presented for the first time in Medtronic's patent owner response?

Holding(s)

The Federal Circuit held that the PTAB erred in refusing to consider Axonics' reply arguments and evidence under the two-input construction. The Federal Circuit vacated the PTAB's decisions in both IPRs and remanded for the PTAB to consider: (1) Axonics' arguments and evidence under the two-input claim construction, and (2) any request to present new evidence brought by Medtronic in its sur-reply.

Where a patent owner offers a new claim construction for the first time in a response after the institution decision, a petitioner may, in a reply brief, introduce new arguments and evidence under the newly proposed claim construction.

More generally, under *Ericsson Inc. v. Intellectual Ventures I LLC*, 901 F.3d 1374 (Fed. Cir. 2018), *Hamilton Beach Brands, Inc. v. f'real Foods LLC*, 908 F.3d 1328 (Fed. Cir. 2018), and *Qualcomm Inc. v. Intel Corp.*, 6 F.4th 1256, 1263 (Fed. Cir. 2021), a petitioner s entitled to respond to new claim construction arguments made after institution by a patent owner or adopted after institution by the Board sua sponte. Both parties are entitled to respond to a new construction adopted after institution by the PTAB sua sponte.

Reasoning

The PTAB's rules (*see* 37 C.F.R. §42.23(b)) and previous Federal Circuit decisions provide that "the petitioner in an IPR proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner." *Apple Inc. v. Andrea Electronics Corp.*, 949 F.3d 697, 706–07 (Fed. Cir. 2020).

To disallow arguments and evidence from petitioners regarding a new claim construction, wherein the new claim construction was first proposed by the patent owner in its final response would: 1) require a petitioner to describe all possible or reasonable claim constructions and present invalidity theories under those constructions in the petition, and 2) create an opportunity for patent owners to sandbag petitioners by sitting on their strongest claim construction arguments until after institution. Outcome 1) is unacceptable because there's no rule calling for such strict requirements on petitioners. Outcome 2) is unacceptable because it would allow patent owners to avoid reaching the merits of the patent owner's strongest claim construction arguments.

Sisvel International S.A. v. Sierra Wireless, Inc.

Nos. 2022-1387, 2022-1492 (Fed. Cir. Sept. 1, 2023)

By: Joshua Weisenfeld

Topic

This case addresses the validity of two patents asserted against wireless communications technologies. In particular, this case discusses claim construction and post-issuance claim amendments that broaden the scope of challenged claims.

Background

Sierra Wireless, along with several other defendants, filed petitions seeking *inter partes* review of U.S. Patent Nos. 7,433,698 (the "'698 patent") and 8,364,196 (the "'196 patent"). The Patent Trial and Appeal Board (the "PTAB") instituted review on both patents and concluded that claims 10, 11, 13, 17, and 23 of the '698 patent and claims 1, 2, 4, and 13-18 of the '196 patent were unpatentable as anticipated and/or obvious in view of the prior art.

Sisvel International S.A. ("Sisvel") appealed both PTAB decisions, challenging the PTAB's construction of the term "connection rejection message," and challenging the PTAB's denial of Sisvel's revised motion to amend the claims of the '698 patent.

Issue(s)

- Whether the claim term "connection rejection message" is limited to specific connection rejection messages issued by telecommunication networks identified in the patent's specification.

- Whether the PTAB erred in denying Sisvel's motion to amend the claims of the '698 patent.

Holding(s)

The Federal Circuit held that the PTAB properly constructed the term "connection rejection message" based on permissive language in the specification.

The Federal Circuit, applying rules set forth by the Administrative Procedure Act ("APA"), held that the PTAB properly denied Sisvel's motion to amend claims of the

'698 patent because the proposed substitute claims, while narrower in parts, were broader than the original claims in at least two limitations of the proposed substitute independent claim.

Reasoning

First, the Federal Circuit considered Sisvel's contention that the PTAB erred in construing "connection rejection message." The Federal Circuit noted that they were applying the *Phillips* claim construction standard – whereby "[t]he words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." Sisvel argued that, in light of the specification, the term "connection rejection message" should be construed as "a message from a GSM or UMTS telecommunications network rejecting a connection request from a mobile station" as the specification specifically identified such telecommunications networks as sending rejection messages. However, the Federal Circuit reasoned that such a construction would improperly limit the claims and that "the intrinsic evidence provide[d] no persuasive basis to limit the claims to any particular cellular network."

Pointing to the specification, the Federal Circuit weighed two disclosures: first, that the specification expressly disclosed embodiments in a GSM or UMTS network, and second, that language from the specification specifically stated "[t]he invention is applicable in any such cellular telecommunication system." The Federal Circuit favored the latter and goes on to agree with the PTAB's decision stating that the cited language from the specification "clearly is permissive, not mandatory." The Federal Circuit concluded that they have no basis, as Sisvel provided insufficient intrinsic evidence, to conclude that a person of ordinary skill in the art would read the broad claim language to be limited to GSM and UMTS networks, and affirmed the PTAB's conclusion that the challenged claim construction should be given its ordinary and customary meaning.

Second, the Federal Circuit considered Sisvel's contention that the PTAB erred by denying its motion to amend the claims of the '698 patent. The Federal Circuit noted that "when a patent owner seeks to amend its claims during *inter partes* review, the amended claims 'may not enlarge the scope of the claims of the patent'" and that "[a] motion to amend may be denied where … [t]he amendment seeks to enlarge the scope of the claims." The Federal Circuit further noted that "[w]hile it is a petitioner's burden to show … that any proposed substitute claims are unpatentable … it is Sisvel's burden … to show that the proposed amendment complies with the relevant regulatory and statutory requirements." The Federal Circuit thus reviewed the PTAB's decision to deny the motion under the APA to determine whether the PTAB's actions were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. In other words, the Federal Circuit reasoned that if the PTAB's determination that the proposed substitute claims were broader in scope than the original claims, was incorrect, the PTAB would have abused their discretion.

However, the Federal Circuit, reviewing the claims de novo, agreed with the PTAB that the proposed substitute claims were broader than the original claims. In coming to this decision, the Federal Circuit looked to instances where the proposed substitute claims were broader than the original claims. The Federal Circuit noted twice that the original claim language required that a value be set "based at least in part on information in at least one frequency parameter" of the connection rejection message and that the substitute claim language merely required the value to be set by "using the frequency parameter" of the connection rejection message. They agreed with the PTAB's distinction that the proposed substitute value need not be based, in whole or in part, on information in the connection rejection message, and thus was broader than original claim 10.

The Federal Circuit rejected Sisvel's argument that "when all of the limitations are considered as a whole, the scope of [the substitute claim] is narrower than the scope of the original claim." The Federal Circuit looked back to the standard set in *Hockerson-Halberstadt* (183 F.3d at 1374) and pointed out that "if a substitute claim 'is broader in any respect [it] is considered to be broader than the original claim[] even though it may be narrower in other respects,'" and concluded that the substitute claim is broader than the original claim. The Federal Circuit, therefore, concluded that the PTAB correctly determined that Sisvel failed to meet its burden to show that the scope of the substitute claims is not broader than the scope of the original claims, and held that the PTAB did not abuse its discretion in finding the same.

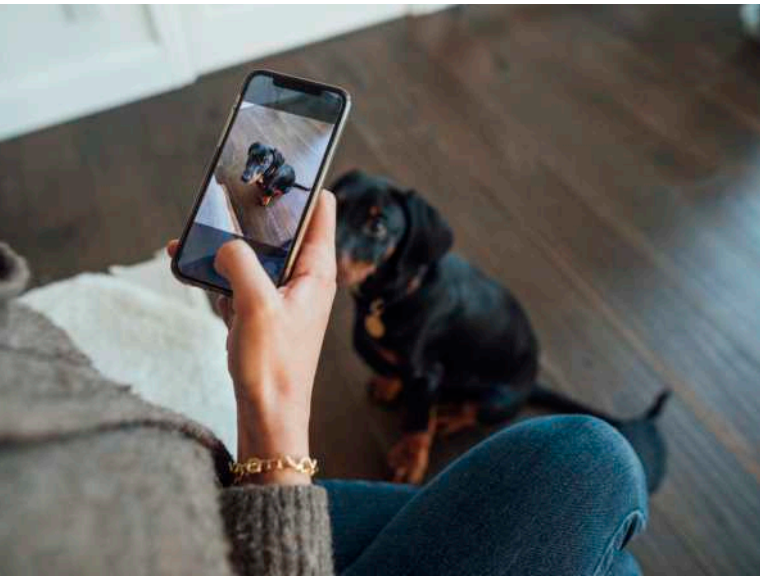
Apple Inc. v. Corephotonics, LTD.

No. 2020-1424 (Fed. Cir. Sept. 15, 2023)

By: Samantha Young

Topic

In this case, the court addressed two final written decisions in *inter partes* review ("IPR") proceedings and in particular (1) whether the Patent Trial and Appeal Board's ("PTAB" or "Board") claim construction is correct when the intrinsic evidence supports a different construction and relatedly whether the PTAB's first final written decision relying on its claim construction should be vacated and remanded and (2) whether, in the second final written decision, the PTAB's reliance on an invalidity ground not raised by any party should be vacated and remanded.



Background

Corephotonics owns the '479 patent, which is directed to creating "portrait photos." Apple filed two IPR petitions, each challenging various claims of the '479 patent as obvious in view of multiple prior art references.

In the first proceeding, the parties disputed the construction of the claim term "fused image with a point of view [("POV")] of the Wide camera." The PTAB agreed with Corephotonics's construction, which was based on the '479 patent's specification equating a camera's POV with how an object will appear in that camera's image plane, including both the position and perspective points of view of the object. Based on this construction, the Board found in its final written decision that the relevant prior art references did not teach the claim limitation that include the disputed term and therefore Apple failed to show that the challenged claims were unpatentable.

In the second proceeding, Corephotonics argued (briefly) in its Patent Owner Response that Apple's expert made a typographical error that altered his calculations, resulting in an inaccurate representation of the prior art's performance. In finding that Apple had not met its burden to show the challenged claims were unpatentable, the Board noted this error as well as additional errors that the Board identified for the first time in its final written decision. During the IPR, neither party had asserted that these errors were material to the claimed invention.

On appeal, Apple challenged the Board's claim construction of the claim term "fused image with a POV of the Wide camera" and challenged the Board's validity findings because they were based on the incorrect claim construction and arguments raised for the first time in the final written decision.

Issue(s)

- Did the PTAB err in limiting its construction of the phrase "fused image with a point of view of the Wide camera" to a single embodiment described in the specification where the specification described multiple embodiments?

- Did the PTAB violate the Administrative Procedure Act ("APA") by raising new arguments in its final decision?

Holding(s)

The PTAB improperly construed the phrase "fused image with a point of view of the Wide camera" because the challenged patent's specification defines multiple types of "points of view," such that the claim should not be limited to the position and perspective points of view.

The PTAB violated the APA by raising new arguments and evidence not contemplated by the parties in any arguments on the merits.

Reasoning

For the first proceeding, the Federal Circuit found that a reasonable reading of the specification suggests that Wide perspective and Wide position are two different types of Wide point of view.

The PTAB explained that the specification describes multiple different points of view while the claims specifically recite "a point of view of the Wide camera." The Federal Circuit found there was no indication that the patentee meant to claim its invention more narrowly that what the specification describes. Therefore, the Federal Circuit found Apple's proposed construction more in line with the intrinsic evidence and vacated the PTAB's decision upholding the challenged claims.

For the second proceeding, the Federal Circuit conceded that the PTAB is entitled to weigh the credibility of the expert witness's statements. But because Corephotonics mentioned the expert's error only once and did not rely on it for any argument on the merits and never argued the error demonstrated there was no reasonable expectation of success, and because the PTAB also relied on errors that both parties agreed did not constitute errors in the first place, the Federal Circuit found the PTAB's decision upholding the challenged claims failed to comport with the APA's notice requirements. Therefore, the Federal Circuit vacated the PTAB's final written decision.

ABS Global, Inc., Genus plc v. Cytonome/ST, LLC

No. 2022-1761 (Fed. Cir. Oct. 19, 2023)

By: Zijian Han

Topic

This case addresses a claim construction issue regarding whether a claim term is plural-allowing.

Background

ABS Global Inc. and Genus plc (collectively, ABS) petitioned for an *inter partes* review of claims 1, 2, 6, 8, and 9 of U.S. Patent No. 10,583,439 (the "'439 patent") owned by Cytonome/ST, LLC. The Patent Trial and Appeal Board ("Board") determined that ABS did not show any challenged claim to be unpatentable. The Board's sole basis was that Simonnet, ABS's primary reference, failed to disclose one limitation, "a fluid focusing region configured to focus the sample stream." This limitation follows the limitation "an inlet configured to receive a sample stream" and precedes the limitation reciting an inspection region. The Board's finding relied on a claim construction for the "fluid focusing region" limitation that requires only a single sample stream from entry of the sample at least to inspection. The Board found Simonnet's figures show a split sample stream with a gap in the middle—i.e., not a single sample stream—and therefore upheld the claims. ABS appealed.

Issue(s)

- Did the Board err in its claim construction that "the sample stream" is limited to a single sample stream?
- Did the Board err in finding ABS has not shown that claims 1, 2, 6, 8, and 9 are unpatentable under the substantial evidence standard?

Holding(s)

- Yes. The Board erred in its claim construction that "the sample stream" is limited to a singular-only sample stream. The Federal Circuit reversed this construction and held that "the sample stream" is not limited to a singular-only sample stream.
- Yes. The Board erred in finding ABS has not shown that claims 1, 2, 6, 8, and 9 are unpatentable under the substantial evidence standard. The Federal Circuit reversed the Board's finding with respect to claims 1

and 8 and found those claims anticipated and vacated the Board's decision with respect to claims 2, 6, and 9 and remanded to the Board.

Reasoning

Claim construction. The Federal Circuit noted that "the sample stream" in the limitation at issue refers back to the earlier-recited "a sample stream" as an antecedent. If "a sample stream" has a plural-allowing meaning, so does "the sample stream."

The Federal Circuit found that, for an open-ended "comprising" claim like claim 1 of the '439 patent, "use of 'a' or 'an' before a noun naming an object requires that the phrase be construed to mean 'one or more' unless the context sufficiently indicates otherwise." *Lite-Netics, LLC v. Nu Tsai Capital LLC*, 60 F.4th 1335, 1345 (Fed. Cir. 2023). Further, the Federal Circuit noted that the '439 patent's specification states that "for the purposes of the present disclosure, the term 'a' or 'an' entity refers to one or more of that entity. As such, the terms 'a' or 'an', 'one or more' and 'at least one' can be used interchangeably herein." The Federal Circuit found that this definition reinforces the applicability here of the "one or more" general rule concerning "a" and "an." The Federal Circuit also noted that neither the prosecution history nor the specification demanded a singular-only meaning.

The Federal Circuit rejected the Board's central argument that a plural-allowing scope would be inconsistent with claim 2, which requires that the focusing fluid be "introduced into the flow channel symmetrically with respect to a centerline of the sample stream." The Board reasoned that "a centerline of the sample stream" must lie in the sample fluid, which, the Board said, would not be true of a centerline (understood as a singular) of a pair of streams or a split stream with a gap in the middle filled by focusing fluid, where the centerline ran through the focusing fluid. However, the Federal Circuit found that the language "**a** centerline" in claim 2 is itself presumptively plural-allowing. The Federal Circuit further held that the Board's reasoning does not address the drawing of separate centerlines for separate streams and that, even for a single centerline for a pair of streams, the claim is broad enough to cover a centerline of a pair of streams. Per the Federal Circuit, a "centerline of the sample stream" is merely a reference point for how focusing fluid should be introduced, which does not preclude a sample-stream centerline from running through focusing fluid.

Validity. For independent claim 1, the Federal Circuit found that under the proper construction "the sample stream" may refer to one or more sample streams and therefore the Simonnet reference satisfies this claim limitation. As the Board found that Simonnet discloses every other element of claim 1 and Cytonome did not meaningfully challenge those findings on appeal, the Federal Circuit held that the evidence compelled a finding that claim 1 is anticipated. Similarly, the Federal Circuit found that the uncontested evidence establishes that Simonnet discloses all limitations of claim 8. Thus, the Federal Circuit reversed the Board's determination and held claims 1 and 8 are anticipated by Simonnet.

As there were unresolved issues with respect to claims 2 and 6—the parties continued to dispute their proper application (and perhaps interpretation)—and with respect to claim 9—the Board has not decided the merits of components of ABS's obviousness challenge, including the motivation to combine Simonnet and Kummrow—the Federal Circuit vacated and remanded these claims to the Board for further consideration.

Malvern Panalytical Inc. v. TA Instruments-Waters LLC

No. 2022-1439 (Fed. Cir. Nov. 1, 2023)

By: Joshua Weisenfeld

Topic

In this case, the Federal Circuit addressed the proper construction of the claim term "pipette guiding mechanism." Specifically, the Federal Circuit found the plain and ordinary meaning of "pipette guiding mechanism" sufficient and addressed how various claim construction doctrines affected its analysis, including the use of a non-related patent cited in an IDS as intrinsic evidence.

Background

Malvern Panalytical Inc. ("Malvern") sued TA Instruments-Waters LLC and Waters Technology Corporation (collectively, "Waters") in the District of Delaware for infringement of various claims of U.S. Patent No. 8,827,549 (the "'549 patent") and its parent, U.S. Patent No. 8,449,175 (the "'175 patent"). The '549 and '175 patents are each directed to isothermal titration calorimeters ("ITC"), which are a specific type of microcalorimeter that measures the amount of energy absorbed or released during a chemical reaction.

During prosecution of a commonly owned, but unrelated patent, U.S. Patent No. 9,103,782 (the "'782 patent"), the examiner rejected various claims as anticipated based on the application that matured into the '175 patent. In particular, the Examiner alleged that the '175 patent's ITC system that manually guided the pipette anticipated the '782 patent's automated ITC system that used an automated guidance system. The applicant, Malvern, unsuccessfully traversed the rejection on the merits, but removed the '175 patent from prior art consideration by arguing that § 103(c)(1) applied, due to common ownership.

After a change in ownership, Malvern sought supplemental examination of the '175 patent under 35 U.S.C. § 257. During the supplemental examination, Malvern cited seven office action documents from the '782 patent prosecution in an IDS and introduced two declarations by the co-inventor Rochalski. Rochalski's first declaration described the ITC device they alleged to have invented, and his second declaration indicated that the features they invented were included in the iTC200 Microcalorimeter, whose user manual was used as an anticipatory reference.

During claim construction, Malvern argued that "pipette guiding mechanism" should mean a "mechanism that guides the pipette assembly," while Waters argued that term should mean a "mechanism that manually guides the pipette assembly." The district court adopted Waters' proposed construction, limiting "pipette guiding mechanism" to manual guided embodiments. The district court reasoned based on an interpretation of the '782 patent's file history that the applicant's statements limited the scope of the '782 patent's "pipette guiding mechanism" to only manual guided embodiments. The district court

considered the statements because the ’782, ’549, and ’175 patents have a common assignee and because both parties and the district court treated the common assignee as Malvern.

Following the district court’s claim construction order, the parties stipulated to non-infringement, which the district court entered. Malvern appealed.

Issue(s)

- Whether the claim term “pipette guiding mechanism” encompasses only manual guiding mechanisms or covers both manual and automatic guiding mechanisms.

- Whether patent documents listed in an information disclosure statement (“IDS”) should be given weight to inform the meaning of “pipette guiding mechanism” in the unrelated ’175 and ’549 patents.

Holding(s)

The Federal Circuit held that the district court erred in concluding that “pipette guiding mechanism” is a coined term with no commonly understood meaning in the art, and instead held that the plain and ordinary meaning of “pipette guiding mechanism” is a mechanism that guides a pipette, which can be either manual or automatic.

The Federal Circuit held that merely listing the ’782 patent office actions in the IDS of the ’175 patent supplemental examination was insufficient to inform the meaning of “pipette guiding mechanism” in the unrelated ’175 and ’549 patents.

Reasoning

First, the Federal Circuit considered whether the claim term “pipette guiding mechanism” encompassed both manual and automatic guiding mechanisms, or was limited to manual guiding mechanisms. The Federal Circuit looked to the claim language, specification, and the co-inventor declarations submitted with the ’175 patent supplemental examination. Specifically, the Federal Circuit considered the plain and ordinary meaning of the term to a skilled artisan at the time of the invention.

The Federal Circuit interpreted the plain and ordinary meaning of “pipette guiding mechanism” to be a mechanism that guides the pipette assembly, and further that it was appropriate to look at the words “pipette,” “guiding,” and “mechanism” individually. The plain language made it “immediately apparent” that the meaning of “pipette guiding mechanism” is a mechanism that guides pipettes, and that the plain and ordinary meaning of the claim language did not contain any restrictions that would indicate such a term is limited to manual mechanisms.

The Federal Circuit considered other claim language and found no support for limiting the assembly to manually guided pipettes. Specifically the panel noted that claim 1 of the ’549 patent specified that the “pipette guiding mechanism” was “arranged to restrict the movement of the pipette assembly along safe paths to ensure that the titration needle cannot be damaged during movement thereof between different positions of operation,” and claim 9 specified that the “pipette guiding mechanism” was “arranged to guide the pipette assembly between and into at least two positions of operations.” The Federal Circuit noted that these “claims clarify and restrict what the guiding mechanism does, but they provide no language suggesting the restriction manual embodiments Waters advocates.” It further noted that the “specification contains no language describing the invention as limited to a manual guiding mechanism, stating that ‘the present invention “is,” “includes,” or “refers to”’ a manual guiding mechanism, or ‘expressing the advantages, importance, and essentiality’ of a manual guiding mechanism.” Importantly, the specification does not disclose whether the guiding mechanism is manual or automatic. The Federal Circuit reasoned that “[t]his absence leads us to conclude that nothing in the specification explicitly or implicitly limits the guiding mechanism to manual embodiments.”

Waters based its argument on portions of the specification and prosecution history of the ’175 patent, which the Federal Circuit found unpersuasive. Accordingly, the Federal Circuit held that the claim language and the specification indicated that the term “pipette guiding mechanism” in the ’549 and ’175 patents should be constructed as a mechanism that guides the pipette assembly either manually or automatically.

Second, the Federal Circuit considered whether the district court erred by concluding that the prosecution history of the ’782 patent was relevant to the construction of “pipette guiding mechanism.” The Federal Circuit noted that “[i]n the absence of an incorporation into the intrinsic evidence, the court’s precedent takes a narrow view on when a related patent or its prosecution history is available to construe the claims of a patent at issue and draws a distinct line between patents that have a familial relationship and those that do not” (*Goldenberg v. Cytogen, Inc.*, 373 F.3d at 1167). It further noted that “even once a

reference has been incorporated into the intrinsic record, such as by citation in an IDS … the amount of characterization of that reference in the IDS impacts how informative we consider the reference when evaluating a patent." In the present case, Malvern's bare listing of the '782 patent office actions in the IDS during supplemental prosecution of the '175 patent did not amount to a material interpretation of the term "pipette guiding mechanism" but instead was merely an admission that the "reference[] in the disclosure may be material to prosecution of the pending claims." Since Malvern merely listed the seven documents from the prosecution of the '782 patent, but did not characterize the documents in any manner, the listing of the '782 patent office action in the IDS of the '175 patent supplemental examination was held to be insufficient to impact the Federal Circuit's understanding of the specification and claim language of the '175 and '549 patents.

Moreover, the Federal Circuit went on to reason that even if the '782 patent's file history were sufficient to consider during construction of "pipette guiding mechanism," the statements in the '782 patent prosecution history did not clearly and unambiguously disclaim any scope of "pipette guiding mechanism." In other words, even though the applicant argued that the '175 application disclosed only a manual guiding mechanism, the Examiner clearly rejected this argument several times, at which point the applicant abandoned this argument. The Federal Circuit reasoned that by abandoning this argument, the applicant acquiesced to the examiner's view that the '175 patent was not limited to manual guiding systems. From this, the Federal Circuit concluded that when an applicant abandons an unsuccessful argument, it is indicative that the prosecution history lacks the clarity necessary to establish prosecution disclaimer.

Actelion Pharmaceuticals Ltd. v. Mylan Pharmaceuticals Inc.

No. 2022-1889 (Fed. Cir. Nov. 6, 2023)

By: Roy Jung

Topic

This case addresses whether a district court needs to consider the extrinsic evidence when the intrinsic record does not sufficiently render the term non-ambiguous.

Background

This is an appeal of the district court's claim construction order. More specifically, this appeal relates to the parties' dispute over the meaning of the limitation "a pH of 13 or higher." In the district court, both "parties proposed the plain and ordinary meaning of the term but disagreed on what that means." Actelion Pharmaceuticals Ltd. ("Appellee" or "Actelion"), took the position that a pH of 13 "would ordinarily encompass those values that round up or down to 13, 12.5 to 13.4" because an ordinary rounding is necessary in view of the three textbooks. Contrarily, Mylan Pharmaceuticals Inc. ("Appellant" or "Mylan") took the position that an ordinary rounding is not necessary. Further, Mylan took the position, that if rounding is necessary, "a pH of 13 would involve rounding to the hundredths place, encompassing

12.995-13.004" based on the three textbooks cited by Actelion. The district court did not address this extrinsic evidence to conclude whether: (i) an ordinary rounding is necessary or (ii) narrower range of rounding is necessary. Rather, the district court agreed with Actelion's proposed construction and issued a claim construction order solely based on findings from the intrinsic record. In particular, the district court stated "under its conventional significant figure meaning, the term a pH of 13 would ordinarily encompass those values that round up or down to 13, 12.5 to 13.4[,]" "the claims consistently expressed a pH of 13 with two significant figures[,] and that the claim language [and prosecution history] provides no basis for inferring any higher level of precision." Based on this claim construction order, the parties stipulated to the final judgment of infringement. Mylan appealed the order.

Issue(s)

- Whether the district court needs to consider the extrinsic evidence when the intrinsic record alone does not establish the clear meaning of a claim term.

Holding(s)

The Federal Circuit reviews claim construction solely based on an intrinsic record *de novo*. The panel found that the disputed claim term remains ambiguous after the "analysis of intrinsic evidence." As such, the district court should have "consider[ed] the extrinsic evidence and its impact on claim construction." Accordingly, the final judgment of infringement is vacated and remanded for further consideration.

Reasonings

The Federal Circuit found the meaning of the disputed term "a pH of 13 higher" "remains unclear even after consulting the specification" and "the prosecution history. " First, the claim language (i.e., "a pH of 13 or higher") alone is not sufficient to conclude the claim is limited to the "specified lower limit." Indeed, "there is no blanket rule that ranges, or specifically open-ended ranges, must foreclose rounding."

Second, lack of an approximation claim language (e.g., about) may not foreclose rounding. Although "absence of approximation language might suggest no approximation," practicality may suggest approximation because "it is not practically possible to measure exact pH values."

Third, disclosure that "[t]he pH of the bulk solution is preferably adjusted to about 12.5-13.4, most preferably 13," may not foreclose rounding. Although such disclosure may show that the patentee "knew how to use approximation language" and "chose not to" use the language, the disclosure also shows that rounding is necessary "or else a preferred embodiment . . . would be excluded from the claim scope."

Fourth, one disclosure that "seems to equate a pH of 13.0 to that of 13" may not foreclose rounding because the specification uses both values with "various degrees of precision."

Fifth, *AstraZeneca AB v. Mylan Pharmaceuticals Inc.* is not applicable. 19 F.4th 1325 (Fed. Cir. 2021). Unlike *AstraZeneca* where rounding resulted with a claim scope that included products the specification explicitly disclosed to exclude, here, no similar evidence exists.

Accordingly, the disputed claim term remains ambiguous after the "analysis of intrinsic evidence." As such, remand for further consideration is necessary because the Federal Circuit may not make factual findings about the extrinsic evidence.

ParkerVision, Inc. v. Katherine K. Vidal

No. 2022-1548 (Fed. Cir. Dec. 15, 2023)

By: Don Geiger

Topic

This case primarily involved three topics: (1) the type of language in a patent specification that "clearly expresses" that the inventor was acting as a lexicographer, i.e., redefining a term against the term's plain and ordinary meaning, (2) the appropriate scope of a reply brief when a patent owner introduces a claim construction for the first time in the patent owner response, and (3) the appropriate scope of a sur-reply brief to a reply brief. The Federal Circuit also engaged in a fact-specific obviousness inquiry regarding capacitor elements disclosed in the prior art.

Background and Procedural History

ParkerVision owned U.S. Patent No. 7,110,444 (the "'444 Patent"), which was directed to frequency translation technology as utilized in wireless local area networks (WLANs). The sole claim at issue recited:

A wireless modem apparatus, comprising:

- a receiver for frequency down-converting an input signal including,
- a first frequency down-conversion module to down-convert the input signal, wherein said first frequency down-conversion module down-converts said input signal according to a first control signal and outputs a first down-converted signal;
- a second frequency down-conversion module to down-convert said input signal, wherein said second frequency down-conversion module down-converts said input signal according to a second control signal and outputs a second down-converted signal; and
- a subtractor module that subtracts said second down-converted signal from said first down-converted signal and outputs a down-converted signal;
- wherein said first and said second frequency down-conversion modules each comprise a switch and a storage element.

ParkerVision sued Intel for infringement of the '444 Patent and Intel filed a request for an IPR. The Board granted institution without construing any claim terms, as neither party had raised any claim construction issues.

ParkerVision filed a patent owner response citing, for the first time, U.S. Patent No. 6,061,551 (the "'551 Patent"), a patent that the '444 Patent incorporated by reference. The '551 Patent disclosed two distinct types of down-converter modules: energy transfer systems, and under-sampled systems. The '551 Patent disclosed "energy transfer systems" as comprising "storage modules," which store non-negligible amounts of energy. In contrast, the '551 Patent disclosed "under-sampled systems" as comprising "holding modules," which store negligible amounts of energy.

ParkerVision's patent owner response relied on the '551 Patent's disclosure to argue that the "storage element" in claim 3 above should be construed as "an element of an energy transfer system that stores non-negligible amounts of energy from an input electromagnetic signal." The patent owner response further argued that cited prior art Tayloe's capacitors were not "storage elements" because they were not part of an energy transfer system.

Intel filed a reply arguing that the '551 Patent did not restrict a "storage element" to being part of an energy transfer system, and therefore prior art Tayloe taught "storage elements" because Tayloe's capacitors stored a non-negligible amount of energy. Intel's reply also provided a proposed construction not limiting "storage element" to being part of an energy transfer system.

ParkerVision filed a sur-reply arguing that prior art Tayloe's capacitors weren't "storage elements" because they only held a negligible amount of energy. This differed from ParkerVision's patent owner response, which argued that prior art Tayloe's capacitors weren't "storage elements" because they weren't part of an energy transfer system. Intel moved to exclude these new arguments from ParkerVision's sur-reply, which the Board granted.

The Board did not accept ParkerVision's proposed construction limiting "storage element" to being part of an energy transfer system. The Board instead accepted the construction from Intel's reply brief, construing "storage element" as "an element of a system that stores non-negligible amounts of energy from an input EM signal," i.e., *not* limited to energy transfer systems.

The Board issued its final written decision determining claim 3 to be unpatentable as obvious over Tayloe in combination with TI Datasheet (another prior art reference). ParkerVision appealed to the Federal Circuit.

Issue(s)

- Did the Board err in construing "storage element" as not limited to being part of an energy transfer system?
- Did the Board err in considering the proposed construction and arguments in Intel's reply brief?
- Did the Board err in excluding ParkerVision's sur-reply arguments addressing the prior art disclosures under Intel's proposed construction?

Holding(s) and Reasoning

(Circuit Judge Chen, writing the opinion for Prost, Wallach, and Chen)

The Board did not err in construing "storage element" as not limited to being part of an energy transfer system.

The Federal Circuit cited recent case law: "To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning and must *clearly express* an intent to redefine the term." *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1378 (Fed. Cir. 2022) (emphasis added). The Federal Circuit considered the following language from the '551 Patent as a clear expression of an intent to redefine "storage element":

[1.] FIG. 82A illustrates an exemplary energy transfer system 8202 for down-converting an input EM signal 8204. [2.] The energy transfer system 8202 includes a switching module 8206 and a storage module illustrated as a storage capacitance 8208. [3.] The terms storage module and storage capacitance, as used herein, are distinguishable from the terms holding module and holding capacitance, respectively. [4.] Holding modules and holding capacitances, as used above, identify systems that store negligible amounts of energy from an under-sampled input EM signal with the intent of "holding" a voltage value. [5.] *Storage [elements] and storage capacitances, on the other hand, refer to systems that store non-negligible amounts of energy from an input EM signal.* '551 Patent, col. 66 ll. 55-64 (emphasis added) (numbering added).

In the Federal Circuit's view, the '551 Patent used reference numerals in sentences [1.] and [2.] to describe a specific embodiment, then the '551 Patent used "as used herein" in [3.] to introduce a general definition for "storage [elements]" in [4.] and [5.]; the general definition in [4.] and [5.] is separate from the specific embodiment disclosed in [1.] and [2.]; the contrast drawn between "holding modules" and "storage [elements]" in [4.] and [5.] utilized comparison to define "storage elements" in [5.]; and finally, the "refer to" language in [5.] showed the intention of the '551 Patent's inventor to define "storage elements" as "systems that store non-negligible amounts of energy from an input EM signal."

The Federal Circuit noted that this construction didn't contradict other embodiments disclosed in the '551 Patent, which only depicted "storage elements" in the context of energy transfer systems, because nothing in the '551 Patent explicitly restricted "storage elements" to being part of energy transfer systems only.

The Board did not err in considering the proposed construction and arguments in Intel's reply brief.

The Federal Circuit reiterated prior case law holding that IPR proceedings are formal adjudications that must satisfy the Administrative Procedure Act ("APA"). The Federal Circuit noted that, under the APA, the Board must provide all interested parties an opportunity to address newly raised arguments. The Federal Circuit further noted that USPTO Rules dictate that a proper petitioner reply brief may only respond to arguments raised in the corresponding patent owner response, opposition, or decision on institution.

According to the Federal Circuit, because Intel's reply brief addressed a claim construction first proposed in ParkerVision's patent owner response, the reply brief was Intel's first opportunity to address ParkerVision's new claim construction of "storage elements." The Board was therefore compelled by the APA to consider the arguments raised in Intel's reply brief. The Federal Circuit pointed to *Axonics, Inc. v. Medtronic, Inc.*, 75 F.4th 1374, 1380 (Fed. Cir. 2023) as a recent example where it reversed the Board's exclusion of reply brief arguments addressing a newly raised claim construction. The Federal Circuit found that Intel's reply brief did not violate USPTO Rules because Intel's proposed construction and arguments addressed a construction raised in the patent owner response.

The Board did not err in excluding ParkerVision's sur-reply arguments addressing the prior art disclosures under Intel's proposed construction.

The Federal Circuit noted that USPTO Rules dictate that a proper patent owner sur-reply brief may only respond to arguments raised in the corresponding petitioner reply brief. The Federal Circuit found that ParkerVision's sur-reply arguments did not respond to arguments raised in Intel's reply brief.

The Federal Circuit explained that the construction raised in ParkerVision's patent owner response required a storage element to both "be an element of an energy transfer system" and "store non-negligible amounts of energy." Therefore, the proposed construction in Intel's reply brief requiring only that storage elements "store non-negligible amounts of energy" did not raise a new argument, as this requirement was already in ParkerVision's patent owner response. ParkerVision decided to only address whether prior art Tayloe taught that storage elements were elements of an energy transfer system; ParkerVision cannot go back to address whether the storage elements store non-negligible amounts of energy simply because Intel's reply brief focused on this requirement.

The Federal Circuit finished by agreeing with the Board's position that, if ParkerVision believed it needed to include arguments and evidence otherwise impermissible in a sur-reply, ParkerVision should have requested authorization for an exception to the USPTO Rules.

Federal Circuit Reverses District Court's Holding of Prosecution Disclaimer and Narrow Claim Construction.

K-fee System GmbH v. Nespresso USA, Inc.

No. 2022-2042 (Fed. Cir. Dec. 26, 2023) ("Opinion")

By: Evan Lim

Topic

This case addresses how the construction of terms in claim limitations is critical in analyzing infringement.

Background

K-fee System GmbH owns U.S. Patent 10,858,176 ("the '176 patent"), U.S. Patent 10,858,177 ("the '177 patent"), and U.S. Patent 10,870,531 ("the '531 patent," and collectively with the '176 patent and '177 patent, "the asserted patents"), which all derive from a single application and share a specification.

K-fee filed a suit against Nespresso USA in the Central District of California ("District Court"), alleging infringement of the asserted patents. The District Court issued a claim-construction order construing certain claim limitations, including the term "barcode" that is present in every claim of the asserted patents. The asserted patents describe and claim coffee-machine portion capsules that use a "barcode" encoded with information that may be read by a device associated with a coffee machine to determine the capsules' compatibility with particular machines and specifications for using the capsules, such as brewing parameters like temperature and amount of water. The District Court construed "barcode" according to its plain and ordinary meaning: a code having bars of variable width, including lines and gaps, and excluding "bit codes" (codes made up of two binary symbols). In issuing this construction, the District Court relied on the intrinsic record, specifically, K-fee's communications with the EPO that were provided to the USPTO, where K-fee stated that a prior art reference, Jarisch, "discloses a 'bit code,' but not a barcode, because the barcode … is always constructed of bars having variable widths, and therefore contains more than only two binary symbols, such as '0' and '1.'" The District Court's construction did not rely on any extrinsic evidence.

Nespresso filed a motion for summary judgment of non-infringement, arguing that its products did not meet the "barcode" limitations under the District Court's construction and that it did not infringe any of the asserted patents.

Nespresso primarily argued that its accused products' capsules operated identically to Jarisch's capsules, which K-fee distinguished before the EPO based on their use of a machine-readable code having only two binary symbols. Given the construction of the term "barcode" to exclude "bit codes," Nespresso argued its code did not meet the "barcode" limitations under their plain and ordinary meaning construction. The District Court reiterated that bit codes using only two symbols could not be claimed "barcodes," placing weight on K-fee's statement to the EPO regarding Jarisch. The District Court found there was no dispute that Nespresso's accused products used a code having only two symbols and concluded that Nespresso therefore did not infringe and thus granted Nespresso's motion.

K-fee appealed.

Issue(s)

- Whether the District Court improperly construed the term "barcode" with a narrowed meaning.

Holding(s)

The Federal Circuit disagreed with and reversed the District Court's construction of "barcode." Given that the construction was the basis for the District Court granting summary judgment, the Federal Circuit reversed and remanded.

Reasoning

On appeal, K-fee argued the District Court improperly narrowed the ordinary meaning of "barcode" by implicitly finding prosecution disclaimer based on K-fee's statements to the EPO. K-fee further asserted the District Court's holding of disclaimer was improper because K-fee's statements to the EPO did not meet the standard of disclaimer.

The Federal Circuit first considered the ordinary meaning of "barcode" in the context of the asserted patents and prosecution history, and then determined whether K-fee surrendered claim scope by clear disclaimer or redefinition.

The Federal Circuit found that "barcode" is used in two different ways in the asserted patents. First, "barcode" refers to an individual message to be read and decoded, e.g., the sequence of bars shown on the bottom side of a flange on a single capsule, so that two different-sequence capsules have two different "barcodes." Second, "barcode" refers to the coding system used to produce the multiple, individual messages, e.g., "the Jarisch code".

Regarding the prosecution history, the Federal Circuit determined that K-fee, in its statements to the EPO, provided evidence in the form of quotes from publications in the field about the meaning of "barcode" to a relevant artisan, where "that the [relevant artisan] at all times defines the term 'barcode' as a line code constructed of bars having variable widths." The Federal Circuit found this understanding is also reflected in a Wikipedia entry and a dictionary entry that K-fee submitted to the District Court. Thus, the Federal Circuit found the ordinary, common-sense, natural English meaning of "bars having variable widths" is a matter of visual appearance: "bars" are two-dimensional shapes having length and width (even if not exactly rectangular), and the widths (in the direction of the linear reading) are not uniform.

The Federal Circuit found that K-fee argued before the EPO that the Jarisch patent did not meet this definition of "barcode" and that under European law, a barcode could not be "directly and unambiguously inferred" from Jarisch because Jarisch disclosed a code whose messages are "formed of a succession of small rectangular surfaces" that can encode two states, corresponding to 0 and 1. As such, the Federal Circuit found that K-fee made its statement to the EPO against this background, in that Jarisch "discloses a 'bit code,' but not a barcode, because the barcode … is always constructed of bars having variable widths and therefore contains more than only two binary symbols such as '0' and '1'." The Federal Circuit further found that K-fee provided additional statements to the EPO, including an expert declaration, noting that "a barcode can be, but is not necessarily, a bit code" and a bit code is "a special form of the binary code," with the expert using the terms "bit code" and "binary code" interchangeably

and stating that "[b]arcodes can therefore principally be regarded as a version of binary codes." In addition, the Federal Circuit found that K-fee's statements clearly provided examples of barcodes, such as retail barcodes, that fell within the scope of the claims, and also clearly presented that a relevant artisan's understanding of "barcode" is that the visual presentation of the coded messages is a series of bars of varying widths, regardless of how the messages are read. This supported K-fee's position that Jarisch's codes are not within the definition of "barcode" because the messages do not visually display bars of varying widths. Hence, the Federal Circuit found that the District Court erred in its analysis of K-fee's statements to the EPO and in its conclusion that a relevant artisan would understand that a barcode must contain more than only two binary symbols, therefore any code that contains only two binary symbols (a bit code) could not be a barcode.

To determine whether K-fee disclaimed or otherwise surrendered claim scope that comes within the claim language, given all the evidence of a relevant artisan's understanding of that language, the Federal Circuit considered whether, despite the apparent ordinary meaning evident from the intrinsic evidence, K-fee "act[ed] with sufficient clarity" before the EPO to "disclaim … [the] plain meaning or prescribe a special definition." The Federal Circuit found no indication that K-fee attempted to redefine the term "barcode," as K-fee did not act as its own lexicographer. The Federal Circuit found K-fee consistently argued before the EPO that its view of barcodes was the ordinary meaning and that K-fee's statements about bit codes were not clear and, if anything, were decidedly ambiguous as a disclaimer, which "must be both clear and unmistakable." Thus, the Federal Circuit found K-fee did not act with the clarity required to either prescribe a new meaning for "barcode" or disclaim any portion of the apparent meaning.

In conclusion, the Federal Circuit found the full scope of the ordinary meaning of "barcode" should apply and the ordinary meaning a relevant artisan would arrive at after reading the intrinsic evidence is that a "barcode" is defined by its visual appearance as lined-up bars of varying widths. As such, the Federal Circuit reversed the District Court's construction of "barcode" and based on that, reversed the summary judgment of non-infringement.

Dionex Softron GmbH v. Agilent Technologies, Inc.

No. 2021-2372 (Fed. Cir. Jan. 6, 2023)

By: Zijian Han

Topic

This case involved the use of co-inventor's testimony to establish priority.

Background

The parties in this case copied claims in separate attempts to provoke an interference. First, Agilent substantially copied Dionex's claims but failed to provoke an interference. Agilent then amended its claims. Dionex subsequently copied those amended claims verbatim, resulting in the interference at issue.

Agilent and Dionex separately moved for judgment on priority due to their respective alleged dates of conception and reduction to practice. The Board, applying the rule of reason, found the testimony of one of Agilent's co-inventors to be sufficiently corroborated by two of his co-workers, who worked near the co-inventor during the relevant time.

Dionex noted that an inventor's testimony must be corroborated by independent evidence. Accordingly, Dionex argued that one of the co-worker's testimony was not independent because he did not appear to know certain aspects of the invention. Dionex further argued that the Board erred in not drawing a negative inference based on the lack of another co-inventor's testimony and certain documentary evidence.

Issue(s)

- Does the rule of reason require a witness to know every detail of the development for his/her testimony to be accepted by the Board for the purpose of corroborating an inventor's testimony?
- Is the Board required to draw a negative inference based on a lack of co-inventor testimony and certain documentary evidence?

Holding(s)

- No. The Federal Circuit found that, under the rule of reason, the omniscience of every detail is not necessary.

- No. The Federal Circuit held that the Board has the discretion to determine whether to apply a negative inference based on what "is reasonable under the totality of evidence in the case."

Reasoning

Under the flexible rule of reason approach, while a co-worker may not have known every detail, such omniscience is unnecessary. The co-worker testified that he witnessed a successful prototype; the Board also found that he understood enough to know that the prototype performed all steps of the interference claim and that the prototype had the depicted configuration. The finding is supported by substantial evidence.

There is no per se requirement to infer that the testimony of an inventor who fails to testify would be harmful to the position of his co-inventor. While the unexplained failure to call any known non-hostile person who has direct knowledge of facts being developed may raise an inference that the testimony would be unfavorable, such an inference is not mandatory. There is similarly no mandate that the Board draw a negative inference when a party fails to present some documentary evidence an opposing party insists must exist. The Board did not abuse its discretion.

In Re: Stingray IP Solutions, LLC

No. 2023-102 (Fed. Cir. Jan. 9, 2023)

By: James Hurt

Topic

This case addresses the Federal Circuit's interpretation of FRCP 4(k)(2) and vacated the district court's transfer order and sent the case back to Plaintiff's originally selected forum.

Background

Stingray filed two suits in the Eastern District of Texas against TP-Link Technologies Co., Ltd. and TP-Link Co., Ltd. Both TP-Link Technologies Co., Ltd and TP-Link Co., Ltd are organized and headquartered in China.

The District Court granted TP-Link's motion to transfer the cases to the Central District of California under § 1406. TP-Link moved to dismiss for lack of personal jurisdiction or, in the alternative, to transfer to the Central District of California under 28 U.S.C. § 1406.[1]

Issue(s)

Was the transfer of the case to the Central District of California based on the defendant's post-suit, unilateral consent to suit in another state proper?

Holding(s)

The Federal Circuit vacated the District Court's decision to grant transfer to the Central District of California and recalled the case back to the Eastern District of Texas.[2]

Discussion

Rule 4(k)(2) was introduced to close[] a loophole that existed prior to the 1993 amendments, by which a nonresident defendant who did not have minimum contacts with any individual state sufficient to support exercise of jurisdiction, but did have sufficient contacts with the United States as a whole, could escape jurisdiction in all fifty states.[3]

Rule 4(k)(2) provides that:

> For a claim that arises under federal law, serving a summons or filing a waiver of service establishes personal jurisdiction over a defendant if:
>
> (A) the defendant is not subject to jurisdiction in any state's courts of general jurisdiction; and
>
> (B) exercising jurisdiction is consistent with the United States Constitution and laws.

Fed. R. Civ. P. 4(k)(2).

District courts are split over whether a defendant can use Rule 4(k)(2) to defeat personal jurisdiction in district A by unilaterally consenting to suit in district B. Some courts have concluded that personal jurisdiction cannot be established under Rule 4(k)(2) when defendants "represent that [they] would be amenable to suit in [another district]."[4] Other courts have concluded that a "defendant must do more than simply say, 'I designate State X as an alternate forum' in order to avoid application of Rule 4(k)(2)."[5]

Court's Decision

The Federal Circuit held that "we see nothing in Rule 4(k)(2) or its history that would permit a defendant to achieve transfer to a preferred district simply by unilateral, post-suit consent."[6] The court looked to notes from an Advisory Committee on Rules of Civil Procedure which made clear that Rule 4(k)(2) was not intended to "affect the operation of federal law[s] providing for the change of venue," §§ 1404(a), 1406, 1631, but was instead envisioned to work in harmony with those provisions to "preclude most conflicts between the full exercise of territorial jurisdiction permitted by this rule and the Fifth Amendment requirement of 'fair play and substantial justice."[7]

In addition, the court noted that the Advisory Committee's notes "do not contemplate that Rule 4(k)(2) may be defeated, and transfer compelled, based on defendant's unilateral, post-suit consent to suit in a different forum… [r]ather, the notes confirm that the typical analysis for "transfer for fairness and convenience under § 1404" applies a standard which does not depend on the "wish or waiver of the defendant."[8]

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[1] *See* In Re: Stringray IP Solutions, LLC, No. 23-102 (Fed. Cir. Jan. 9, 2023).

[2] Id at *2. "The District Court granted TP-Link's motion to transfer the cases to the Central District of California under § 1406."

[3] *See* Touchcom, Inc. v. Bereskin & Parr, 574 F.3d 1403, 1414 (Fed. Cir. 2009).

[4] *See* Lambeth Magnetic Structures, LLC v. Toshiba Corp., No. 14-1526, 2017 WL 782892, at *6 (W.D. Pa. Mar. 1, 2017).

[5] *See See* MediaZam LLC v. Voices.com, Inc., No. 20-cv-1381, 2022 WL 993570, at *12 (E.D. Wis. Mar. 31, 2022). Compare, e.g., Fitbit, Inc. v. Koninklijke Philips N.V., 336 F.R.D. 574, 582–85 (N.D. Cal. 2020); Alpha Tech. U.S.A. Corp. v. N. Dairy Equip., Ltd., No. 6:17-cv-1000, 2018 WL 501598, at *5 (M.D. Fla. Jan. 22, 2018), with Knoll, Inc. v. Senator Int'l Ltd., No. 19-4566, 2020 WL 1922780, at *6–9 (E.D. Pa. Apr. 21, 2020); Mitsui O.S.K. Lines, Ltd. v. Swiss Shipping Line S.A.L., No. 17-cv-3394, 2017 WL 6327538, at *3–4 (N.D. Cal. Dec. 6, 2017).

[6] *See* In Re Stingray at *10.

[7] *See* Advisory Committee Notes on 1993 Amendment to Fed. R. Civ. P. 4, May 1993.

[8] *See* In Re Stingray at *11.

In Re: Google LLC

No. 2022-1012 (Fed. Cir. Jan. 9, 2023)

By: Joshua Weisenfeld

Topic

This case addresses obviousness under 35 U.S.C. § 103 in relation to an amendment to overcome prior art, i.e., whether a reference disclosing a threshold can be combined with a reference disclosing a search-query-intent score to render obvious a threshold based on the number of words in query. In general, modification of a reference with teachings from another reference can only be upheld when it is adequately argued by the Examiner during prosecution.

Background

Google responded to a § 103 rejection by amending claims in the '093 application (drawn to methods for filtering the results of an internet search query such that only results appropriate for the user [e.g., age appropriate] are displayed) to recite that the predetermined threshold value (for determining whether content was appropriate) is "determined based on a number of words included in the search query." The Examiner acknowledged that the primary reference, Parthasarathy, did not disclose a threshold based on a number of words, but alleged the secondary reference, Rose, did via its modified relevance-ranking algorithm, and that the combination of the two references read on the amended feature. Google responded to the office action and argued that Rose only discloses a query-length-dependent relevance score, and that the score itself was not a threshold value. Google further argued that the combination may increase the score based on the number of words, but that the combination still failed to teach whether a score was below a threshold that itself depended on query length. The Examiner disagreed and Google appealed to the Board. The Board agreed with Examiner citing Examiner's modification argument such that modifying Parthasarathy's threshold "to take into account query length as taught by Rose" would have been obvious. Google appealed to the Federal Circuit following this decision.

Issue(s)

- Whether a reference disclosing a threshold value modified by a reference disclosing a query length rendered obvious a feature claiming a threshold value based on search query length.

- Whether arguments presented to the Federal Circuit, but not sustained by the Board's decision can maintain a rejection of claims.

Holding(s)

The combination of a threshold value and query-length score does not render obvious a feature claiming a threshold value based on a search query length.

Arguments presented by the PTO to the Federal Circuit that were not substantiated by the prosecution history cannot be introduced to maintain an obviousness rejection on appeal.

Reasoning

On appeal, the PTO argued that there were only two ways to predictably modify Parthasarathy's threshold to incorporate query length as taught by Rose. However, this is contrary to the Board's decision that was based on a finding that modifying Parthasarathy with Rose would have been obvious to try, it did not discuss or suggest the specific modifications the PTO advanced on appeal. The Federal Circuit reasoned they cannot adopt the PTO's fact-based arguments in the first instance on appeal. The PTO further attempted to base their arguments in quotes from the Examiner, however, the Federal Circuit noted that none of the Examiner's quotes suggested how such a technique was conventional or widespread. The PTO further conceded on appeal that there is no record evidence that supports a finding that using query length as a threshold was well known in the art.

Additionally, the PTO conceded that Rose does not disclose a predetermined threshold based on a number of words. Rather, it discloses a method of calculating result-dependent relevance scores, one that can necessarily only be implemented after the results of the query are retrieved. Unlike a predetermined threshold, which applies to a collection of search results, Rose's relevance score will in general vary from result to result. Simple substitution of Rose's score for Parthasarathy's user-selected threshold cannot provide the predetermined threshold of Google's claims.

Personalized Media Communications, LLC v. Apple Inc.

No. 2021-2275 (Fed. Cir. Jan. 20, 2023)

By: Samantha Young

Topic

This case addresses various factual considerations when evaluating prosecution laches. In general, prosecution laches requires showing that (1) the patentee's delay in prosecution is unreasonable and inexcusable under the totality of circumstances and (2) the accused infringer suffered prejudice attributable to the delay.

Background

Personalized Media Communications ("PMC") sued Apple in the U.S. District Court for the Eastern District of Texas, alleging that Apple's FairPlay infringed claim 13 (and related dependent claims) of U.S. Patent No. 8,191,091 ("the '091 patent"). A jury found that Apple infringed at least one of the claims. Subsequently, a bench trial found the '091 patent unenforceable based on prosecution laches. The district court found that PMC engaged in an unreasonable and unexplained delay amounting to an egregious abuse of the statutory patent system.

The district court based its finding on several factual underpinnings. First, PMC maintained an agreement that required prosecution of a first application followed by a second, related application, evidencing intentional delay. Furthermore, PMC reintroduced a previously rejected claim to the application. The court concluded that "the only rational explanation for PMC's approach to prosecution is a deliberate strategy of delay" and that "PMC's actions were a conscious and egregious misuse of the statutory patent system."

As to prejudice, the court explained that Apple had already begun developing the accused FairPlay system by 2003, the year that PMC first added the asserted technology to the '091 patent's predecessor. The patent also issued seven years after FairPlay had already matured into the accused version. Therefore, the district court concluded that Apple was prejudiced.

Issue(s)

- Does the asserted conduct have to be similar to previous cases on prosecution laches?
- Does compliance with an institutional agreement and the USPTO rules preclude prosecution laches?
- Can delay by the USPTO excuse the asserted conduct for prosecution laches?
- Does the number of applications filed by a party indicate unreasonable delay?
- Do narrowing amendments preclude unreasonable delay?
- Is an expert required to assert prosecution laches?
- Does the number of patents issued to a party indicate a lack of unreasonable delay?
- Can a court consider criticism from the USPTO in determining a party's unreasonable delay?

Holding(s)

Conduct asserted for prosecution laches does not have to resemble the previous cases.

Compliance with an institutional agreement and the USPTO rules does not preclude prosecution laches. In fact, the agreement may be further evidence of prosecution laches.

The USPTO's delay does not excuse an applicant's delay.

The number of applications can indicate unreasonable delay when combined with other relevant and supporting facts.

The fact that amendments narrow the claim does not mean that unreasonable delay cannot occur.

An expert is not necessary to assert prosecution laches.

The number of issued patents does not preclude a finding of unreasonable delay in light of other supporting facts.

The USPTO's criticism of a party's prosecution methods can serve as additional evidence of an unreasonable delay.

Reasoning

Laches is an equitable and flexible doctrine that requires the court to consider the totality of the circumstances. Even if similarity to previous cases was required, the present case involved institutionalizing abuse of the patent system by expressly adopting and implementing dilatory prosecution strategies. Furthermore, "[a]n applicant must ... not only comply with the statutory requirements and USPTO regulations but must also prosecute its applications in an equitable way." As to delays by the USPTO, "a delay by the PTO cannot excuse the appellant's own delay."

The district court properly considered the fact that PMC filed 328 GATT-Bubble applications because the district court faulted PMC for waiting until 2003—sixteen years after the priority date of the '091 patent and nearly eight years after PMC filed its 328 GATT-bubble applications—to include the key limitations to the claims. As to the need for an expert, there was no basis in the record to suggest that the district court needed an expert's specialized knowledge to help understand the administrative records and the USPTO regulations in this case. Furthermore, the fact that the USPTO issued many patents to PMC does not suggest clear error, especially given how many other facts weigh against PMC here. The court also properly considered the context of the USPTO's criticisms and reasonably weighed them in view of other evidence.

In Re: Google LLC

No. 2023-101 (Fed. Cir. Feb. 1, 2023)

By: Sofya Asatryan

Topic

Google petitioned for writ of mandamus directing the Western District of Texas to vacate its order denying Google's motion under 28 U.S.C. § 1404(a) to transfer, and to transfer the case to the Northern District of California.

Background

Jawbone filed a patent infringement suit against Google in the Western District of Texas, less than one year of being assigned ownership of the asserted patents and incorporating in Texas. Google moved to transfer the action to the Northern District of California.

Google argued that the relevant technology used in the accused products were researched, designed, and developed at Google's headquarters in California; the technology at issue was also developed in California.

Further, Google's key personnel with knowledge about the technical and financial issues, and four of the six inventors who were named in the complaint were located in California.

On balance, the court concluded that Google had failed to demonstrate that the Northern District of California was clearly more convenient, and denied the motion.

Issue(s)

- Did the district court clearly abuse its discretion in denying Google's motion to transfer?

Order

The Federal Circuit determined that the district court abused its discretion and granted Google's petition. It vacated the district court's order denying Google's motion to transfer, and directed the district court to grant the transfer motion.

Reasoning

Pursuant to 28 U.S.C. § 1404(a), a district court may transfer any civil action to any other district court where the action might have been brought for the convenience of parties and witnesses and in the interest of justice.

- The district court incorrectly gave too much weight to Jawbone's co-pending litigations in the same district. Notably, the Court also reasoned that there should be no weight given to the expected time to trial because Jawbone does not directly compete with Google and there was no need for a quick resolution.

- The district court should have weighed the cost of attendance for willing witnesses heavily (not slightly) in favor of transfer.

- The court incorrectly held the "local interest" factor was neutral because Jawbone conducts no activities from Texas that relate to the accused technology. The patented and accused technology were both developed in California, and it was clear error not to find that the local interest factor favored transfer.

Cywee Group Ltd. v. Google LLC

Nos. 2020-1565, 2020-1567 (Fed. Cir. Feb. 8, 2023)

By: Theo Mayer

Topic

This case addresses administrative and constitutional challenges to *inter partes* review (IPR) decisions in the aftermath of the Supreme Court's and Federal Circuit's *Arthrex* decisions ("Arthrex I" and "Arthrex II" respectively).

Background

In 2018, Google challenged CyWee's patents in two IPRs. The Patent Trial and Appeal Board (PTAB) instituted, and extended its standard 12 month statutory period for final written decision by one month due to joinder of additional parties.

The PTAB found all challenged claims were unpatentable for obviousness. CyWee appealed, arguing that the PTAB's administrative patent judges (APJs) were unconstitutionally appointed.

The Federal Circuit rejected CyWee's constitutional challenge based on its then-binding precedent – *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019). However, 11 days after the Federal Circuit issued its mandate in CyWee's appeal, the Supreme Court partially reversed the Federal Circuit's *Arthrex* decision. Namely, in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021) ("*Arthrex I*"), the Supreme Court held the PTAB's unreviewable authority during IPR violated the Appointments Clause. The Supreme Court remedied the Appointments Clause violation by giving the USPTO Director discretion to review and reverse PTAB decisions (referred to colloquially as "Arthrex Challenges").

After *Arthrex I*, CyWee requested rehearing of its IPR decisions by the USPTO Director. The request for rehearing was referred to the Commissioner for Patents, who denied rehearing and ordered the PTAB's decisions as the final decisions of the agency.

CyWee again appealed.

In its initial appeal brief, CyWee made another Appointments Clause challenge arguing the Commissioner of Patents lacked proper authority to issue a final decision binding the Executive Branch. This issue was quickly swept aside by the Federal Circuit in view of its decision in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 35 F.4th 1328 (Fed. Cir. 2022) ("Arthrex II") – which held that the Commissioner of Patents can "issue a final decision binding the Executive Branch" on a "temporary, acting basis," under the Appointment's Clause.

Issue(s)

- Must the USPTO Director perform (or at least be able to perform) the review set forth in *Arthrex I* within the statutory periods for institution of IPRs and issuance of final written IPR decisions?

- Did the PTAB have authority to extend the 12 month statutory for issuance of final written due to joinder of additional parties?

Holding(s)

The USPTO Director is not required to review the PTAB's institution and final written decisions within their applicable statutory periods – the review can be later.

The PTAB had authority to extend the 12 month statutory for issuance of final written decisions due to joinder.

Reasoning

The Federal Circuit did not find persuasive CyWee's arguments that the USPTO Director must perform (or at least be able to perform) the review set forth in *Arthrex I* within the statutory periods for institution of IPRs and issuance of final written IPR decisions. The Court reasoned: (1) the applicable statutes simply state when an institution must be made and when a final written decision must be issued; (2) the USPTO Director permissibly delegated those decisions to the PTAB, and the PTAB made timely decisions; and (3) nothing in the statutes required USPTO Director review of the PTAB's decisions within their applicable statutory periods.

The Federal Circuit also reasoned that the PTAB had authority to extend the 12 month statutory for issuance of final written decisions because the USPTO Director had permissibly delegated "that time-adjustment authority to the [PTAB]."

Lite-Netics, LLC v. Nu Tsai Capital LLC

No. 2023-1146 (Fed. Cir. Feb. 17, 2023)

By: Don Geiger

Topic

This case addresses federal preemption of state tort liability for speech about patent rights (e.g. cease-and-desist letters). In addition, this case applies the "objective baselessness" standard for determining bad faith in cease-and-desist letters.

Background

Lite-Netics holds two patents claiming holiday light strings, wherein the individual lights have magnetic bases for securing the lights to metal siding. Representative claim language reads:

1. A light fixture assembly, comprising: [...] a base attached to the [end] of the light bulb socket, and a [magnet] embedded in the base, wherein said magnet [has] a pull strength of at least five pounds.

Nu Tsai Capital LLC, dba "Holiday Bright Lights" ("HBL"), is a competitor in the holiday lights market. HBL sells a Magnetic Cord product, wherein two separate magnets, each having a pull strength less than five pounds, are embedded in the bases of light bulb sockets. HBL additionally sells a Magnetic Clip product, wherein a magnetic base can be held against the base of a light bulb socket by clipping to the light bulb socket's wires.

Lite-Netics sued HBL in the District of NE, and subsequently sent cease and desist letters to mutual customers (i.e. holiday lighting retailers) of both Lite-Netics and HBL. The cease and desist letters informed the retailers that HBL is the subject of a patent infringement suit and insinuated that Lite-Netics will bring suit against the recipient retailer if they resell HBL's products.

HBL sought a preliminary injunction based on counterclaims of tortious interference with business relations and defamation under NE law. After an evidentiary hearing, the district court granted a preliminary injunction preventing Lite-Netics from communicating with HBL customers suggesting the customers may be sued, or suggesting that HBL is a patent infringer.

Lite-Netics appealed.

Issue(s)

- Does federal patent law preempt state tort liability for speech about patent rights?

- Did the district court abuse its discretion in granting a preliminary injunction against Lite-Netics' speech about its patent rights?

Holding(s)

Federal patent law preempts state tort liability for speech about patent rights, to the extent that such speech was made in good faith. When communications are in bad faith, state tort liability may be found.

The district court abused its discretion in granting a preliminary injunction against Lite-Netics' speech about its patent rights. The preliminary injunction is vacated and the case remanded for further proceedings.

Reasoning

Federal preemption of tort liability for speech about patent rights is supported by:

- The interest of having a uniform jurisprudence regarding nationally scoped patent law;
- Established general federal exclusivity in patent cases; and
- First Amendment principles. First Amendment concerns are particularly strong when considering an injunction against speech, as was granted here.

Federal patent law requires a showing of bad faith before state tort liability may survive preemption, and bad faith requires a showing of "objective baselessness." Objective baselessness cannot be found where a patent holder simply misconceives what their rights are, as long as there remains an objectively reasonable basis for their allegations such that success could realistically have been expected on the merits.

Federal patent law also required HBL to show a likelihood of success on its merits before granting a preliminary injunction affecting Lite-Netic's speech about patent rights. Therefore, in order to show a likelihood of success on the merits sufficient for a preliminary injunction, HBL needed to show at least that Lite-Netic's could not have realistically expected success in an infringement suit when Lite-Netic alleged that HBL had infringed Lite-Netic's patents in the cease-and-desist letter.

The Federal Circuit considered Lite-Netics' arguments that:

1. HBL's Magnetic Cord product contained multiple combined magnets exceeding five pounds of pull strength on one base, which infringes the "magnet" language despite the multiple magnets not being arranged as a single unitary magnet, and
2. The "attached" claim language reads on HBL's Magnetic Clip holding of a magnet against the bottom of a light bulb socket's base.

The Federal Circuit found these arguments to have objectively reasonable basis such that Lite-Netic could have realistically expected success on the merits in an infringement case. Further, the Federal Circuit found no language in the patent, in the patent's file wrapper, or in case law supporting the District Court's holding that Lite-Netics' assertions of literal and/or doctrine of equivalents infringement by HBL were "objectively baseless." Therefore, the district court abused its discretion in granting the preliminary injunction.

Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals

No. 2023-1186 (Fed. Cir. Feb. 24, 2023)

By: Takuma Nishimura

Topic

This case addresses the scope of the Orange Book listings for patents.

Background

Jazz Pharmaceuticals, Inc. ("Jazz") sued Avadel CNS Pharmaceuticals, LLC, ("Avadel") for infringement of U.S. Patent No. 8,731,963. Jazz holds an approved New Drug Application ("NDA") for a GHB based Xyrem, a medication to treat narcolepsy. The '963 patent claims "a computer implemented system" that controls access to drugs prescribed specifically to narcolepsy patients. The '963 patent was included in the Orange Book as covering a method of using Xyrem, which was required as part of a Risk Evaluation and Mitigation Strategies ("REMS") to prevent the drug's use as a date-rape drug. The '963 patent expired on December 2022, but because Jazz received a grant of pediatric exclusivity, the inclusion of the '963 patent in the Orange Book prevented the FDA from approving follow-on products until June 2023.

In December 2020, Avadel submitted an NDA for GHB-based drug FT218 pursuant Sec 505(b)(2). FT218's REMS uses multiple pharmacies and databases for ensuring proper drug handling. Despite filing as NDA and not ANDA, the FDA required Avadel to file a certification regarding the '963 patent's single pharmacy system. Jazz subsequently sued Avadel for infringement of the '963 patent.

Avadel contemporaneously sued the FDA for violating Administrative Procedure Act by requiring certification over the '963 patent. However, the FDA does not verify that submitted patents actually meet statutory listing criteria, nor does the FDA proactively remove improperly listed patents. Instead, Avadel sought the other remedy for an improper listing, which is to file a counterclaim when sued seeking an order requiring the patent owner to correct or delete a listing under 21 U.S.C. § 355(c)(3)(D)(ii)(I).

The FDA suit was dismissed and the district court overseeing Jazz v. Avadel ordered Jazz to defile the patent. Jazz appealed the district court's decision for abuse of discretion.

Issue(s)

- Was it abuse of discretion for the '963 patent to be delisted within the Orange Book by the district court?

Holding(s)

District court's delisting of the '963 patent was proper.

Reasoning

21 U.S.C. § 355(c)(3)(D)(ii)(I) permits an accused infringer to seek an order requiring the patent owner to correct or delete Orange Book listings "on the ground that the patent does not claim either … the drug for which the application was approved; or … an approved method of using the drug."

The Federal Circuit found that in order to answer this question, the district court must determine what the patent claim by using tools and framework of patent law, including claim construction. The district court found that each of the three independent claims of the '963 patent claimed a system, not a method. Specifically, the district court highlighted that the each independent claim describes a "computer-implemented system" that comprises "one or more computer memories" and a "data processor." The district court concluded and the Federal Circuit agreed that a system claim is not equivalent to a method claim under the framework of patent law.

The Federal Circuit then turned to the question of whether the '963 patent claims "an approved method of using the drug" as defined by Section 355. The Federal Circuit held that "method" used in context of method-of-use patent for medication does not broaden the definition of the term method. Rather, the category is narrowed to those that (1) claim methods of use, wherein (2) those methods of use are directly relevant to the NDA in question. Because the '963 patent claims a system, Section 355 does not apply to the '963 patent.

Jazz also points to the phrase "conditions of use." However, the "conditions of use" applies when evaluating efficacy, not to define the method of use. Therefore, the "conditions of use," referenced by Jazz does not expand the meaning of method of using the drug.

Jazz also argued that courts should take deference to FDA's interpretation of Section 314.53. However, the Federal Circuit held that the current issue is not based on interpretation. Furthermore, even if there was language ambiguity, the FDA did not definitively answer the question whether REMS patents should be more broadly listed in the Orange Book. The FDA opened several notice-and-comment inquiries, but has yet to make a formal response. Because FDA has yet to provide a formal response regarding this interpretation, the district court did not intrude on FDA's deference.

Apple Inc. v. Vidal

No. 2022-1249 (Fed. Cir. Mar. 13, 2023)

By: Joshua Weisenfeld

Topic

This case addresses the United States Patent and Trademark Office ("USPTO") Director Katherine Vidal's instructions to the Patent Trial and Appeal Board ("PTAB"), regarding the exercise of discretion in *inter partes* review ("IPR") institution decisions. In particular, this case discusses notice-and-comment rulemaking under the Administrative Procedures Act ("APA") in relation to Director Vidal's IPR institution instructions.

Background

Apple and others, challenged USPTO Director Vidal's instructions to the PTAB on how to exercise discretion in institution decisions for IPR petitions. The particular instructions challenged are the so-called "*Fintiv* instructions" which provides a framework for discretionary denials for patents that are also subject to co-pending district court litigation.

Apple brought the suit under the APA, 5 U.S.C. §§ 701-706, alleging three grounds: (1) that Director Vidal acted contrary to the IPR provisions of the patent statute; (2) that the *Fintiv* instructions are arbitrary and capricious; and (3) that the *Fintiv* instructions were issued without compliance with the notice-and-comment rulemaking procedures under 5 U.S.C. § 553. The District Court dismissed all claims put forth by Apple, holding that the Director's instructions were unreviewable per 35 U.S.C. §§ 311-319.

Issue(s)

- Whether USPTO Director Vidal was required to promulgate institution instructions to the PTAB through notice-and-comment rulemaking procedures.

Holding(s)

The Federal Circuit separated the procedural requirements set forth in the APA from the underlying substance of the rule and reopened Apple's claim that the Director was required to promulgate institution instructions through notice-and-comment rulemaking procedures. The Federal Circuit also found that Apple had standing to bring this

claim. However, the Federal Circuit affirmed the District Court's dismissal of content-based claims, as the IPR statute clearly precludes judicial review of such claims. The Federal Circuit remanded the case for further proceedings on whether the Fintiv instructions were properly issued without adhering to notice-and-comment rulemaking procedures as provided for under the APA.

Reasoning

The Federal Circuit separated Apple's claims into content-based claims, which address the content of Director Vidal's instructions, and procedural claims, which address the general procedure in which she promulgated the instructions.

The Federal Circuit then affirmed the dismissal of the first two claims as being directed to content-based issues (i.e., what the content or substance of the instructions were), which the Federal Circuit held was well within the Director's discretion to issue. Under a plain meaning analysis and clear Supreme Court precedent, the IPR statute precluded judicial review of content-focused challenges to the *Fintiv* instructions under 35 U.S.C. § 314(d).

Next, the Federal Circuit found that the procedural requirements set forth in the APA provide a separate analysis of reviewability from the substance of the instructions. The Federal Circuit reiterated that the IPR statute precludes content-based judicial review, but the IPR statute does not authorize the Director to forego notice-and-comment rulemaking procedures when issuing instructions for the PTAB regarding when to institute IPRs.

The Federal Circuit also found that Apple had standing to bring the claim that the USPTO Director was required to promulgate institution instructions through notice-and-comment rulemaking procedures, as there was a genuine possibility that the instructions would be changed in a favorable way to Apple.

Philip Morris Products S.A. v. International Trade Commission

RAI Strategic Holdings, Inc. (Intervenors)
No. 2022-1227 (Fed. Cir. Mar. 31, 2023)

By: Sofya Asatryan

Topic

This case involved Federal Circuit review of an ITC Section 337 ruling ordering Philip Morris to stop importing and selling its vape tobacco products because they infringed on Reynolds' patents.

Background

Philip Morris and Reynolds compete in the tobacco consumer market, including vape tobacco products. Reynolds filed a complaint with the International Trade Commission (ITC) alleging that Philip Morris' IQOS line of electronic nicotine delivery system products violated Section 337 through its importation and sale of tobacco products.

The ITC affirmed the ALJ's findings that (1) the accused IQOS products infringed Reynolds' patents; (2) Reynolds established the existence of a domestic industry, and (3) the public interest did not weigh against entry of a limited exclusion order. The ITC issued cease and desist orders to Altria Client Services LLC and Philip Morris USA, Inc. The ITC also issued a limited exclusion order banning the importation of infringing products by Philip Morris and its affiliates.

Issue(s)

- Whether the ITC failed its statutory duty under 19 U.S.C. § 1337(b)(2) to "consult with, and seek advice and information from" the Department of Health and Human Services (HHS), specifically the Food and Drug administration (FDA), during the Section 337 investigation;

- Whether the ITC abused its discretion by granting injunctive relief notwithstanding the evidence Philip Morris provided on public interest;

- Whether the ITC's finding that a domestic industry exists was legally erroneous because the products on which Reynolds relied for its assertion of domestic industry had not received FDA approval at the time the complaint was filed;

- Whether the ITC's findings showed the asserted claims of the '123 patent would have been obvious;

- Whether the ITC's conclusion that the accused products infringed the asserted claims of the '915 patent rested on an erroneous claim construction; and

- Whether the ITC incorrectly concluded that Philip Morris failed to show that the asserted claims of the '915 patent are invalid because the allegedly invalidating product does not qualify as prior art.

Holding(s)

- The ITC satisfied its duty to "consult with" HHS and committed no error.

- The ITC properly considered and weighed the public interest evidence put forth by the parties and did not abuse its discretion.

- The economic prong of the domestic industry analysis does not exclude products that have not received FDA approval at the time of filing the complaint and the ITC's finding of a domestic industry was proper.

- The Federal Circuit affirmed the ITC's rejection of invalidity of the '123 patent due to obviousness.

- The ITC committed no error in its determination that Philip Morris' accused IQOS products infringe the '915 patent.

- The Federal Circuit affirmed the ITC's final decision that expert testimony from Philip Morris was insufficiently corroborated to establish an invalidating public use of the invention claimed in the '915 patent.

Reasoning

Philip Morris forfeited its argument that the ITC failed to "consult" with the HHS and the FDA because despite having numerous opportunities to raise and preserve this issue, it raised the duty to consult argument for the first time on its motion to stay the cease and desist orders and LEO remedies. Nonetheless, the ITC satisfied its duty by providing these agencies notice and an opportunity to comment on the public interest matters.

The ITC did not abuse its discretion by granting injunctive relief because its decision rested on a reasonable review of the public interest evidence. The evidence included expert testimony, scientific evidence, and most importantly, over 30 FDA documents regarding the IQOS products. Several FDA documents showed that the exclusion of the IQOS products would not adversely impact the public health and welfare because the FDA found all tobacco products are potentially harmful and addictive. The Federal Circuit also noted that there are non-tobacco alternative therapies available to the public.

19 U.S.C. § 1337(a)(2)–(3) does not require that the protected articles have federal regulatory approval and Philip Morris pointed to no such authority. Also, the record demonstrated that the FDA had knowledge that Reynolds sold its products in the United States at the time of filing.

Philip Morris failed to prove claims 27-30 of the '123 patent as obvious over U.S. Patent No. 5249586 ("Morgan") because of its lack of discussion of the heating elements being centrally placed. The Federal Circuit agreed with the ITC's reasoning that "the '123 patent's disclosure did not support Philip Morris' assertions that choosing heating element placements was a simple design choice or that there was a finite number of known solutions for such placements."

The Federal Circuit found Philip Morris' "claim construction" argument as an attempt to reconstrue the claims and rejected it. Philip Morris failed to challenge the claim language "receiving end" during the ITC proceeding and was precluded from challenging it again.

The Federal Circuit found that the ITC did not err in adopting the ALJ's findings and conclusions because Philip Morris relied on oral testimony in an attempt to invalidate the '915 patent. When a witness's "testimony alone is asserted to invalidate a patent" courts impose a corroboration requirement because a witness may forget or make mistakes in their recollection. Philip Morris relied on testimony from a former product management team leader, Mr. Burton. The Federal Circuit agreed with the ALJ that while Mr. Burton's testimony may have established that devices known as "Accord K" were in public use in Florida by at least 2006, Philip Morris failed to show that the Accord K devices used there were the same as the devices described in the technical documents that Philip Morris relied on in its invalidity arguments.

Ironburg Inventions Ltd. v. Valve Corp.

No. 2021-2296 (Fed. Cir. Apr. 3, 2023)

By: Theo Mayer

Topic

This case addresses the "skilled and diligent searcher" standard used for establishing *inter partes* review ("IPR") estoppel (or lack thereof). In particular, this case establishes: (1) which party bears the burden of proof regarding whether a "skilled and diligent searcher" could have reasonably been expected to discover prior art such that failure to include it in an IPR petition estops the petitioner from raising it in other civil actions under 35 U.S.C. § 315(e)(2); and (2) the "skilled and diligent searcher" inquiry itself with respect to what a skilled and diligent searcher reasonably would have been expected to discover.

Background

In 2015, Ironburg Inventions Ltd. ("Ironburg") sued Valve Corporation ("Valve") for infringing U.S. Patent No. 8,641,525 ("the '525 patent"). Valve also filed an IPR petition, which the PTAB instituted on two of the four asserted grounds.

Before the district court, Valve raised four grounds of invalidity. The district court held: (1) Valve was estopped from litigating two of the grounds because they were included in the IPR petition, but not instituted (the "Non-Instituted Grounds"); and (2) Valve was estopped from litigating the other two grounds (the "Non-Petitioned Grounds") not raised in the IPR petition because Valve failed to prove a "skilled and diligent searcher" could not have been reasonably expected to discover the Non-Petitioned Grounds prior to the petition.

At trial, Ironburg was awarded a verdict of willful infringement and awarded damages of over $4 million. Both parties appealed on multiple grounds (not all of which are discussed here for brevity) – including whether Valve was properly estopped from litigating the Non-Petitioned Grounds.

Issue(s)

- Who bears the burden of proof regarding what prior art references a "skilled and diligent researcher" could have reasonably been expected to discover that could have formed the basis for an invalidity challenge in an IPR petition?

- What is the burden of proof?

Holding(s)

The party asserting IPR estoppel (typically a patent owner) bears the burden of proving that a "skilled and diligent searcher" could have been reasonably expected to discover prior art that could have formed the basis of an invalidity challenge in an IPR petition. Accordingly, the district court incorrectly placed the burden on Valve (i.e., the non-asserting party) to prove a "skilled and diligent searcher" could not have been reasonably expected to discover the Non-Petitioned Grounds.

A party asserting IPR estoppel must prove, "by a preponderance of the evidence, that a skilled searcher conducting a diligent search reasonably would have been expected to discover" Non-Petitioned Prior Art Grounds. In other words, the proper inquiry is not "what an actual researcher in fact *did* find through whatever level of diligence she exercised," but is what the skilled searcher "*would* find through reasonable diligence."

Reasoning

A party asserting IPR estoppel bears the burden of proof because it is "the party asserting and seeking the benefit from the affirmative defense of IPR estoppel." This reasoning is consistent with the general principle that "a party asserting an affirmative defense bears the burden to prove it."

The "skilled searcher" standard "is consistent with the statutory requirement that a petitioner be estopped from asserting 'any ground that the petitioner . . . reasonably could have raised during . . . *inter partes* review.'"

Healthier Choices Management Corp. v. Philip Morris USA, Inc.

No. 2022-1268 (Fed. Cir. Apr. 12, 2023)

By: Takuma Nishimura

Topic

This case addresses pleading standards in view of contradicting factual assertions and a complaint's disavowal of statements in an exhibit.

Background

Healthier Choices Management Corp. ("HCM") sued Philip Morris for patent infringement accusing Philip's "electronic nicotine delivery system" called the IQOS system. HCM's patent claims an electronic smoking device, that includes a limitation that recites a "combustible material reservoir" that "initiat[es] a combustion reaction in the combustible material reservoir."

Philip Morris markets the IQOS system as a "heat-not-burn" system, claiming that the heat does not result in burning of the tobacco. HCM included an exhibit in its original complaint Philip Morris' Modified Risk Tobacco Production Application (MRTPA). Philip Morris argued that the MRTPA showed that the IQOS did not initiate a combustion reaction and thus Philip Morris did not infringe.

The district court agreed with Philip Morris and dismissed the complaint. HCM moved for leave to file an amended complaint, removing its reference to the MRTPA and attached an expert declaration opining that the IQOS system resulted in some burning and therefore the IQOS infringed the patent.

However, the district court determined that the HCM failed to plausibly allege, in either the original or the amended complaint, that the IQOS system initiates a combustion reaction and thus denied HCM's motion for leave to amend the complaint.

Issue(s)

- Did the district court err by dismissing the original complaint?
- Did the district court err by denying HCM's motion for leave to amend the complaint?

Holding(s)

The district court erred on both issues.

Reasoning

Regional circuit law applies when reviewing motions to dismiss for failure to state a claim under Rule 12(b)(6). Under the Eleventh Circuit law, a district court can consider exhibits attached to a complaint in ruling on a motion to dismiss and if the allegation of the complaint about a particular exhibit conflicts with the contents of the exhibit itself, the exhibit controls. But this does not mean that factual assertions made in an exhibit always control over contrary factual assertions on the same subject made in a complaint. Similarly, when a complaint contains specific, well-pleaded allegations that either do not appear in the attached exhibit or that contradict conclusory statements in the exhibit, courts in the Eleventh Circuit credit the allegations in the complaint.

In its original complaint, HCM disagreed with Philip Morris' MRTPA and specifically referred to defendant's test result that specified "97%, not 100%, of the harmful chemicals associated with combustion are eliminated by the Accused Infringing Product," and combustion markers were still present. This allegation explained why HCM disagreed with Philip Morris's characterization in the MRTPA of the IQOS system as combustion-less. The Federal Circuit found that these allegations were neither general nor conclusory since they were supported by defendant's own tests. The allegation successfully asserted a plausible theory for why the IQOS system might nonetheless initiate combustion despite Philip Morris' contrary marketing. The Federal Circuit reasoned that when construing the complaint in a light most favorable to the plaintiff and accepting as true all facts the plaintiff alleges, the allegations were sufficient to disavow the contradictory statements in the MRTPA.

In the Eleventh Circuit, district courts may consider a document outside the pleading and treat it as part of the pleading for purposes of Rule 12(b)(6) if the document is "(1) central to the plaintiff's complaint; and (2) undisputed." HCM did not attach the MRTPA in its amended complaint and removed any citations to the MRTPA, but continued to allege that combustion occurs in the IQOS system. HCM included an expert declaration that contained testimony that concluded combustion.

The Eleventh Circuit "do[es] not permit a district court to consider, on a motion to dismiss, exhibits attached to an earlier complaint that a plaintiff has expressly disavowed or rejected as untrue in a subsequent amended complaint." There is no requirement of magic words to disavow statements made in an exhibit. HCM disavowed the statements contained in the MRTPA in its original complaint and its exclusion from the amended complaint also satisfies the disavowal.

HIP Inc. v. Hormel Foods Corp.

No. 2022-1696 (Fed. Cir. May 2, 2023)

By: Roy Jung

Topic

This case addresses the requirements necessary to establish a *prima facie* case to correct inventorship under 35 U.S.C. § 256.

Background

Hormel Foods appealed the District Court's ruling that David Howard should be added as a joint inventor on its patents.

Standard of Review

"Inventorship is a question of law that [the Federal Circuit] review[s] without deference." The Federal Circuit "review[s] facts underlying inventorship for clear error."

Claimant's Burden of Proof and Requirements to Establish a Prima Facie Case

Under the *Pannu* factors, to qualify as a joint inventor, "an alleged joint inventor must prove by clear and convincing evidence" that an alleged joint inventor (i) "contributed in some significant manner to the conception of the invention[,]" (ii) "made a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention[,]" and (iii) "did more than merely explain to the real inventors well-known concepts and/or the current state of the art."

Issue(s)

- Whether Mr. Howard is a joint inventor based on the significance of his alleged contribution.

Holding(s)

Mr. Howard is not a joint inventor because he has not made any significant contribution to the invention.

Reasoning

Mr. Howard is not a joint inventor because his alleged contribution was not significant when measured against the scope of the full invention. "[T]he specification, claims, and figures [of the patent-at-issue] illustrate that Howard's alleged contribution . . . is insignificant in quality when measured against the dimension of the full invention." For example:

- Mr. Howard's contribution is "mentioned only once in the" specification of the patent-at-issue "as an alternative";
- Mr. Howard's contribution is "recited only once in a single claim" of the patent-at-issue. Further, such contribution is recited in a Markush group;
- The "[s]ummary of the invention" of the patent-at-issue does not mention Mr. Howard's contribution; and
- No figure or recited example described Mr. Howard's contribution.

United Cannabis Corporation v. Pure Hemp Collective Inc.

No. 2022-1363 (Fed. Cir. May 8, 2023)

By: Samantha Young

Topic

This case addresses whether attorney's fees are warranted due to an inequitable conduct and conflict of interest defense.

Background

UCANN filed suit in the District of Colorado in July 2018, accusing Pure Hemp of infringing the '911 patent, entitled "*Cannabis* Extracts and Methods of Preparing and Using the Same." The parties stipulated to the dismissal of this case in 2021. On April 14, 2021, Pure Hemp moved for an award of attorney fees pursuant to 35 U.S.C. § 285, 28 U.S.C. § 1927, and the district court's inherent authority. Pure Hemp asserted that (1) UCANN's prosecution counsel had allegedly committed inequitable conduct by copying text from a piece of prior art, U.S. Patent Publication No. 2004/0033280 ("Whittle"), into the specification of the '911 patent and then not disclosing Whittle to the USPTO as prior art; and (2) UCANN's litigation counsel, Cooley LLP, purportedly took conflicting positions in its representation of UCANN and another client, GW Pharma (the owner of Whittle). Pure Hemp timely appealed.

Issue(s)

Did the district court err in denying attorney's fees for:

- failing to find Pure Hemp to be the prevailing party in the litigation;
- not concluding that the undisputed facts establish inequitable conduct; and
- not recognizing that UCANN's attorneys had a conflict of interest for which they should be sanctioned?

Holding(s)

The district court did not err in finding that Pure Hemp was not entitled to attorney's fees, though the district court did err in failing to find that Pure Hemp was the prevailing party.

Reasoning

The Federal Circuit found that Pure Hemp successfully rebuffed UCANN's lawsuit and "ensured that UCANN can never again assert the same patents against Pure Hemp's same accused products." Therefore, the district court erred in failing to find Pure Hemp to be the prevailing party. However, the Court found that this error was harmless because the district court did not abuse its discretion in finding that the case was not exceptional as to warrant attorney's fees. The Court found that the district court did not have to conduct further proceedings on the inequitable conduct argument and, based on the existing record, there was a genuine dispute as to whether Pure Hemp could satisfy its burden of proof. Therefore, because the record demonstrates a genuine dispute as to the material fact of intent and the materiality of the conduct, Pure Hemp failed to meet its burden to prove that this case is exceptional due to inequitable conduct. Pure Hemp asserted that the Federal Circuit could make its own findings on intent to deceive and materiality. However, the Court affirmed that it could not make its own findings of fact. Pure Hemp also argued that the district court failed to provide a more fulsome analysis. The Court rejected this contention because it has not imposed a blanket requirement that a district court must provide its reasoning in attorney fee cases. Finally, the Court found that Pure Hemp waived its conflict of interest argument because it did not cite Rule 1.7 of the Model Rules of Professional Conduct to the district court before citing it to the Federal Circuit. Furthermore, there was also no evidence presented that the patents Cooley prosecuted and obtained were identical. Pure Hemp failed to show that Cooley acted adversely to the interests of UCANN or GW Pharma. As a final matter, the Court narrowly found that the appeal was not frivolous because while the position was weak, it was not frivolous, as evidenced by the fact Pure Hemp won on the point that the district court erred in failing to find it as the prevailing party.

OneSubsea IP UK Ltd. v. FMC Tech., Inc.

No. 22-1099 (Fed. Cir. May 23, 2023)

By: Zachary Alper

Topic

This case addresses the proper standard for an appeal of a discretionary decision by a successor judge as well as requests for attorneys' fees under 35 U.S.C. § 285 and certain circumstances that *do not* make a case exceptional.

Background

In 2016, OneSubsea brought an infringement suit against FMC alleging infringement of ten patents directed generally to "subsea recovery of production fluids from an oil or gas well." The crux of OneSubsea's infringement theory came down to "whether fluid flows through FMC's accused device as required by the OSS patents."

During claim construction, the District Court ruled that the term "divert," as used in the asserted patents, means "the direction of the fluid's flow is forced to change from its current flowpath to a different flowpath." FMC used the District Court's claim construction as the basis for a motion for summary judgment of noninfringement, which OneSubsea opposed.

Rather than immediately deciding the summary judgment motion, the District Court stayed the case pending the outcome of parallel *inter partes* reviews ("IPRs") at the Patent Trial and Appeal Board challenging the validity of the asserted patents. In reaching this decision, the District Court noted that "it is unclear from the current record whether FMC's dispositive motion would be granted."

The IPRs were decided three years later, leaving infringement litigation alive, at which point the District Court lifted the stay and reinstated the case. Ultimately, the parties filed renewed summary judgment motions, with OneSubsea electing to use a different expert than they used in their original opposition to FMC's summary judgment motion. In response, and at the *sua sponte* direction of the District Court, FMC moved to exclude the new expert's testimony under Federal Rule of Evidence 702 and *Daubert* for failure to take the District Court's *Markman* order into account when performing the infringement analysis, which the District Court granted. The District Court then granted FMC's motion for summary judgment, noting that without expert testimony to support their infringement arguments, OneSubsea "has failed to present admissible evidence of more than a single flowpath through . . . [FMC's accused device].

Following the District Court's grant of summary judgment in favor of FMC, FMC filed a motion for attorneys' fees and non-taxable costs under 35 U.S.C. § 285. FMC argued that it was entitled to an exceptional case finding justifying attorneys' fees under § 285 because of OneSubsea's "substantively weak" and "objectively baseless" infringement theories, and a host of litigation misconduct theories, including presenting an expert witness who disregarded the District Court's claim construction order, misrepresenting to FMC which of the infringement claims had been dropped throughout the litigation, and unreasonably prolonging the case. With briefing completed for the motion for attorneys' fees, but prior to a decision on the motion, the presiding judge retired, and the case was transferred to Judge Bennett. Judge Bennett denied FMC's motion for attorneys' fees, which FMC appealed.

Issue(s)

- Abuse of Discretion and Successor Judges: Is the abuse of discretion standard proper for an appeal of a discretionary decision by a successor judge?

- Exceptional Case Findings Under 35 U.S.C. § 285: When a District Court allows a case to proceed after summary judgment, can a party obtain an exceptional case finding by complaining that the opposing party's legal theories are "objectively baseless"?

Holdings

- Abuse of Discretion and Successor Judges: Yes – the abuse of discretion standard is proper for appeals to discretionary decisions by a successor judge.

- Exceptional Case Findings Under 35 U.S.C. § 285: No – declining to end a case on summary judgment effectively confirms that the infringement theories advanced by the patentee (at least those at issue in the summary judgment motion) are not "objectively baseless."

Reasoning

Abuse of Discretion and Successor Judges: FMC argued that under the Supreme Court's ruling in *Highmark*, the de novo standard should be used in this case because the ultimate decision on the § 285 motion was made by Judge Bennett, who had no exposure to the multi-year proceedings prior to the § 285 motion. The Federal Circuit rejected FMC's arguments, citing extensive case law "in which appellate courts have consistently reviewed successor judges' decisions on discretionary issues for abuse of discretion." While carving out a potential to apply the higher de novo standard in situations in which credibility determinations were deemed material to the outcome of the case, the Federal Circuit noted that FMC did not adduce any evidence as to why the Federal Circuit would be better positioned to decide the motion than Judge Bennett.

Exceptional Case Findings Under 35 U.S.C. § 285: FMC argued that OneSubsea's infringement theories were objectively baseless after the District Court's claim construction ruling on the term "divert." The Federal Circuit promptly rejected FMC's arguments, noting that the District Court did not grant the original motion for summary judgment, instead commenting that it was "unclear from the current record whether FMC's dispositive motion would be granted," and even noting in 2019 that OneSubsea originally "had an expert to raise a fact issue." As the Federal Circuit explained, "[w]hen a district court, fully aware of the competing contentions of the parties, declines to end the case on summary judgement and allows a plaintiff's case to proceed, the district court may have effectively determined that the position of the party opposing summary judgment is not objectively baseless, making it nearly impossible for the plaintiff's case (on the issue that was the subject of the summary judgment motion) to 'stand out' as lacking substance at that time."

Blue Gentian, LLC v. Tristar Products, Inc.

Nos. 2021-2316, 2021-2317 (Fed. Cir. June 9, 2023)

By: Takuma Nishimura

Topic

This case addresses requirements to correct inventorship of a patent.

Background

Blue Gentian is an assignee of Michael Berardi's six patents involving a collapsible hose, where Berardi is the named inventor. Three months before filing the applications for the six patents, Gary Ragner held a meeting to seek investors, which included Berardi. During the meeting, Ragner showed documents detailing the manufacturing process of a collapsible hose and demonstrated a prototype of the hose. The prototype hose included a wire spring to force the hose to a retracted state, about which Berardi asked whether the spring can be replaced with elastic and Ragner responded that his first two prototypes used elastic. Within hours after the meeting, Berardi built his own prototype and three months later filed a patent application, which was granted as one of the six patents. The other five patents involve subject matter related to the first patent. Tristar counterclaimed to correct the inventorship of the six patents. The district court ordered correction of the inventorship for the six patents holding that Ragner should have been a named co-inventor for all of the asserted patents. Blue Gentian appealed, alleging error in the district court's determination that:

1. Ragner sufficiently contributed to conception;
2. there was sufficient evidence of corroboration of Ragner's testimony; and
3. there was sufficient evidence of collaboration between Ragner and Berardi.

Issue(s)

- Did the district court commit error by ordering correction of inventorship?

Holding(s)

The district court did not commit error in ordering correction of inventorship.

Reasoning

Regarding the first alleged error, Blue Gentian argued a proper contribution analysis requires claim construction before finding contribution and contributed elements must be sufficiently tied to specific claims.

The Federal Circuit held that since the district court resolved the questions about claim scope raised in the patent, it was under no obligation to address other potential ambiguities, i.e., courts are not required to "prospectively address hypothetical claim-construction disputes."

Regarding Blue Gentian's argument about the sufficiency of ties between contributed elements and claims, the Federal Circuit highlighted it was undisputed that each of the asserted patents includes one or more claims that require Ragner's design elements that distinguished the claims from prior art. The Federal Circuit held that slight differences in appearance from the disclosed design elements do not amount to a new and separate design conception and therefore these elements were sufficiently tied to the claims. Accordingly, the district court did not commit error by holding that Ragner contributed his design elements to each one of the asserted patents.

Blue Gentian argued that Ragner's contributions were not the same claimed elements, the contributed elements were already present in prior art, and the contributed elements were already conceived by Berardi before the meeting. The Federal Circuit found Blue Gentian overly narrowed the scope of analysis. The Federal Circuit elaborated that the proper scope in deciding contribution considers the elements in combination. The Federal Circuit also held that what matters is the significance of the overall contribution, not the significance of individual elements standing alone. Furthermore, Blue Gentian did not present evidence of Berardi's prior conception. Accordingly, the Federal Circuit held the district court did not commit error in finding that Ragner had sufficiently contributed to the claims.

Regarding the second error, the Federal Circuit held Tristar's evidence was sufficiently corroborated by both physical and circumstantial evidence. The district court correctly considered evidence as a whole and drew reasonable inferences from the circumstantial evidence.

Finally, regarding the third error, the district court correctly found that there was sufficient collaboration between Berardi and Ragner based on the information that was exchanged at the meeting. It is insignificant that Berardi ultimately designed an alternative design based on the information exchanged during the investment procurement meeting. It is also insignificant that Ragner did not conceive the entire invention or have the intent to make the invention before he started collaborating. Accordingly, the district court did not commit error by ordering correction of the inventorship to add Ragner as a co-inventor.

Medytox, Inc. v. Galderma S.A.

No. 2022-1165 (Fed. Cir. June 27, 2023)

By: Roy Jung

Topic

This case addresses: (i) whether Medytox's proposed substitute claims introduce new matter, and satisfy the written description and enablement requirements and (ii) whether "the Board's revision of its claim construction [position]. . . made between a preliminary guidance and a final written decision ("FWD") violates the Administrative Procedure Act ("APA")."

Background

The patent-at-issue relates to the "use of an animal-protein-free botulinum toxin composition that exhibits a longer lasting effect in patient compared to an animal protein-containing botulinum toxin comparison." Galderma challenged the patent-at-issue through a post-grant review. In response, patentee Medytox filed a motion to the Board to cancel claims of the patent-at-issue and substitute with new claims and requested "the Board to issue a preliminary guidance in accordance with the pilot program concerning the motion to amend practice and procedures." The Board issued a preliminary guidance that the proposed substitute claims do not introduce new matter based on its construction of the limitations "responder rate at 16 weeks after the first treatment of 50% or greater" to mean "simply 50% or greater," not "range of 50-100%." The Board concluded the substitute claims do not introduce new matter because the specification discloses responder rates higher than 50%.

The Board later revised its claim construction from "simply 50% or greater" to "range of 50-100%" in its FWD. And the Board concluded based on this construction, the substitute claims do introduce new matter because "the specification only disclosed responder rates of up to 62%." Further, the Board found that even if the proposed substitute claims do not introduce new matter, the claims should not be permitted because the substitute claims are unpatentable as they lack written description and are not enabled after considering the *Wands* factors—"a skilled artisan would not have been able to achieve [] responder rates [higher than

62%] . . . without undue experimentation." Based on these grounds, the Board denied Medytox's motion to amend substitute claims. Medytox appealed this decision.

Issue(s)

1. Whether the proposed substitute claims introduce new matter.

2. Whether the proposed substitute claims satisfy the written description and enablement requirements.

3. Whether the Board's decision to revise its claim construction position between a preliminary guidance issued through its Pilot Program concerning motion to amend practice and a FWD violates the APA.

    - Whether the Board's preliminary guidance issued through its Pilot Program concerning motion to amend practice is binding.
    - Whether the decision to revise its claim construction position was arbitrary and capricious.
    - Whether the Board's lack of notice to revise its claim construction prevented Medytox from a full and fair opportunity to litigate the case.

Holding(s)

The Federal Circuit reviews the Board's legal conclusions *de novo* and its factual findings for substantial evidence. In particular, "[w]hether a claim amendment satisfies the written description requirement or improperly adds new matter are both questions of fact reviewed for substantial evidence." Claim construction and whether a claim is enabled are issues of law that may involve underlying factual findings. Based on this standard of review, the Federal Circuit held that Medytox's proposed substitute claims introduce new matter and did not satisfy the written description and enablement requirements. The panel concluded that the Board's did not violate the APA. Accordingly, the Federal Circuit affirmed the Board's decision.

Reasonings

The Federal Circuit found substantial evidence supports the Board's FWD that the proposed substitute claims introduce new matter. Although the Board initially opined in its preliminary guidance that the substitute claim limitations "responder rate at 16 weeks after the first treatment of 50% or greater" do not introduce new matter, it later revised the opinion in its FWD that the proposed substitute claims do introduce new matter. The Board's decision to revise its claim construction position was based on its findings that "responder rate" should be construed to mean "50-100%" and "the specification only disclosed responder rates of up to 62%." The Federal Circuit found these grounds are substantial evidence sufficient to support the Board's FWD. Accordingly, the Federal Circuit affirmed the Board's FWD that the proposed substitute claims introduce new matter.

The Federal Circuit affirmed the Board's finding that the proposed substitute claims do not satisfy the written description and enablement requirements. In its FWD, after considering the *Wands* factors, the Board concluded proposed substitute claims do not satisfy the description and enablement requirements because: (i) Medytox failed to show how to modify the disclosed formulations to achieve the claimed ranges and (ii) the specification disclosed at most 62% responder rate. The Federal Circuit found that these findings are substantial evidence that supports the Board's FWD that the proposed substitute claims do not satisfy the written description and enablement requirements.

The Federal Circuit concluded the Board's decision to revise its initial preliminary guidance opinion did not violate the APA. First, the Board did not violate the APA because Board's preliminary guidance is "preliminary" and is "non-binding." Second, the Board did not violate the APA because the Board has authority under *In re Magnum Oil Tools Int'l, Ltd.* to revise its claim construction position if not arbitrary and capricious. 829 F.3d 1364 (Fed. Cir. 2016). Here, the Board's decision to revise its claim construction position was not arbitrary and capricious because it was "based on totality of the record." *Id.*; *see also* above. Third, the Board did not violate the APA because Medytox had a full and fair opportunity to litigate the case. The Board "revised the scheduling order for the parties to develop new evidence and arguments" when Galderma filed an opposition to dispute the construction. Also, Medytox had an opportunity to challenge the Board's FWD construction when it filed a Request for Director Review or Panel Rehearing, but decided not to do so. Accordingly, the Federal Circuit concluded the Board did not violate the APA.

Inguran, LLC, DBA STGenetics v. ABS Global, Inc., Genius PLC

No. 2022-1385 (Fed. Cir. July 5, 2023)

By: Samantha Young

Topic

This case addresses the issue of res judicata and the interpretation of the scope of an earlier judgment awarding an ongoing royalty.

Background

In 2006 and 2012, ABS and STGenetics entered into related contracts for sorting semen. In 2014, ABS filed an antitrust lawsuit in the Western District of Wisconsin against STGenetics. STGenetics brought counterclaims and third-party claims for, among other things, infringement of the '987 patent. ABS stipulated to direct infringement of certain claims and the jury awarded STGenetics a "lump sum for ABS's past infringement in the amount of $750,000, and a per straw royalty on future sales of sexed semen straws sold by ABS of $1.25."

In 2020, STGenetics filed another lawsuit against ABS in the Western District of Wisconsin to assert, among other things, additional patent infringement claims based on the'987 patent (also asserted in the first suit), including induced infringement. ABS moved to dismiss the induced infringement claims on the grounds that they were precluded by the judgment in the first suit. The district court agreed with ABS and dismissed the action. Further, regarding the ongoing royalty, the district court stated that "the judgment [in the first suit] is reasonably interpreted to cover straws produced by third parties using GSS technology as licensed by ABS." STGenetics appealed both the district court's finding of claim preclusion and its interpretation of the ongoing royalty.

Issue(s)

- Does the district court's finding of direct infringement in the first suit preclude induced infringement claims in the later suit?

- Does the scope of the district court's ongoing royalty award cover straws produced by third parties using GSS technology as licensed by ABS?

Holding(s)

The first suit did not preclude STGenetics from bringing induced infringement claims in a later suit because induced infringement was not the subject of the first suit and the operative facts surrounding the induced infringement differed from those of the first suit.

The district court abused its discretion in expanding the scope of the damages award in the first lawsuit as it relates to the ongoing royalty because the original royalty awarded did not include third-party manufacturing.

Reasoning

Res judicata. The court analyzed claim preclusion based on Seventh Circuit law, which compares the identity of the parties and the claims asserted. The same cause of action is asserted where the second claim is based on the same set of transactional facts as the first. The Court found there was no support in the record of the first suit that STGenetics asserted or cited induced infringement against ABS for actions taken by third parties as a result of ABS's activities. Furthermore, the Court found that the induced infringement claim brought in the later suit was not precluded by the direct infringement finding in the first suit because the claims were not based on the same transactional facts. Namely, the first suit centered around ABS's activity for direct infringement, while the later suit's induced infringement claims centered around direct infringement based on the acts of third parties. The Court explained that STGenetics needed additional facts to plausibly allege induced infringement, facts that came to light during discovery in a lawsuit involving the parties that was filed between the two above lawsuits. Even though there was some evidence in the first suit that ABS induced third parties to infringe the '987 patent, the Court still found no claim preclusion because the infringement allegations in the later suit were temporally limited to acts occurring after final judgment in the first suit.

The scope of the ongoing royalty. A district court's interpretation of the scope of equitable authority and its orders is reviewed based on abuse of discretion. The Court found that the plain language of the royalty is limited to straws made by ABS. While "GSS technology" is mentioned throughout the first suit, the Court reasoned that the scope of ABS's direct infringement allegations cannot reasonably be expanded to cover actions of third-party licensees using GSS technology to make their own straws in light of its reasoning that induced infringement was not precluded by the first suit. Accordingly, the district court improperly broadened the scope of the judgment to cover induced infringement activity.

SNIPR Technologies Ltd. v. Rockefeller University

No. 22-1260 (Fed. Cir. July 14, 2023)

By: Zachary Alper

Topic

This case addresses certain implications of the *Laehy-Smith* America Invests Act (AIA), namely whether patents with a filing date after March 16, 2013 (pure AIA patents) may be part of an interference proceeding under pre-AIA, 35 U.S.C. § 135, and specifically whether the Patent Trial and Appeal Board (Board) has the authority to cancel SNIPR's pure AIA claims through an interference for lack of invention priority under pre-AIA § 102(g).

Background

In 2011, Congress passed the AIA, which transformed the U.S. patent system from a first-to-invent system to a first-to-file system. Under a first-to-invent system, the first person to come up with an invention has "priority" and is entitled to a patent even if there was an earlier filed patent application from a different inventor covering the same invention. Under the pre-AIA regime, an inventor could challenge the priority of an earlier filed application in an administrative proceeding called an "interference" in order to demonstrate an earlier invention date. Under a first-to-file system, the first person to file a patent application has "priority" regardless of the invention date. As part of switching from a first-to-invent system to a first-to-file system, Congress removed "interference" proceedings from the AIA because it was no longer necessary to determine who invented first. The text of the AIA makes clear that all patents with a filing date prior to March 16, 2013 would continue to be governed by the pre-AIA legislation while any patent with a filing date on or after March 13, 2016 would be governed by the AIA – as well as the limited circumstance of a mixed-AIA patent, which is subject to the pre-AIA for claims with a priority date prior to March 16, 2013, and is subject to the AIA for claims with a priority date on or after March 16, 2013.

With the statutory background established, enter SNIPR and Rockefeller, two companies that own patents/applications covering similar techniques for CRISPR gene editing. At issue in this dispute were five SNIPR patents that claimed priority to a PCT application filed on May 3, 2016 (pure AIA), as well as a Rockefeller patent application with an effective filing date of February 7, 2013 (pre-AIA).

During the prosecution of the Rockefeller application, the Board declared an interference between claims 20–33 of the Rockefeller applications and all claims of the SNIPR patents to determine which party was the first to invent. Due to the earlier filing date of the Rockefeller application and the failure of SNIPR to file a priority statement asserting an invention date earlier than the Rockefeller application's earliest priority date, the Board determined that Rockefeller had senior party status and cancelled all claims of the SNIPR patents.

SNIPR twice moved to terminate the interference proceedings, but the Board denied each request reasoning that "pre-AIA patent claims (such as Rockefeller's) must comply with [pre-AIA] 35 U.S.C. § 102(g)[.]" SNIPR then appealed to the Federal Circuit.

Issue(s)

- Whether interference proceedings apply to pure AIA patents that are being challenged based on a pre-AIA patent?

Holding(s)

No, patents with a priority date on or after March 16, 2013 are not subject to interference proceedings regardless of whether the interfering patent has a filing date before March 16, 2013.

Reasoning

SNIPR argued that its inclusion in an interference proceeding was improper because its patents, having priority dates after March 16, 2013, were governed solely by the AIA, which eliminated interference proceedings. Rockefeller argued that interference proceedings under pre-AIA § 135 authorized the Director to declare an interference between an application that would interfere with "any unexpired patent," including the SNIPR patents. The Federal Circuit rejected Rockefeller's arguments in light of the statutory interpretation of both the AIA and pre-AIA. First, they interpreted the text of the AIA, noting that § 3(n) specifically enumerates that the AIA applies to patents filed on or after March 16, 2013 and the pre-AIA regime applies to patents filed prior to March 16, 2013. Additionally, the Federal Circuit found no hints in the text of the AIA that Congress intended to subject pure AIA patents to the cost and complexities of interference proceedings. As a consequence, the AIA bars pure AIA patents from being subject to an interference.

Rockefeller also argued that a pure-AIA patent should be allowed in an interference proceeding based on language in pre-AIA § 135(a) which authorized the Director to declare an interference between any interfering application (in this case, Rockefeller's) and "any unexpired patent" (in this case, SNIPR's). Rockefeller argued that the language "any unexpired patents" applied to pure-AIA patents, which would allow for an interference including SNIPR's pure-AIA patents. The Federal Circuit again rejected these arguments, providing that interpreting "any expired patent" to include pure-AIA patents would defeat a central purpose of the AIA (moving to a first-to-file system and avoiding the cost and inefficiencies of interference proceedings) and would render superfluous the statutory scheme delineating between pure-, pre-, and mixed-AIA patents.

United Therapeutics Corp. v. Liquidia Technologies Inc.

No. 2022-2217 (Fed. Cir. July 24, 2023)

By: Fred Chung

Topic

The Federal Circuit reviewed the district court's decision on invalidity and infringement of two pharmaceutical patents and the impact of the Final Written Decision (FWD) in a parallel *inter partes* review (IPR) upon the district court's decision.

Background

Liquidia filed a New Drug Application for Yutrepia™, its non-generic dry powder inhalation formulation of the drug treprostinil, under § 505(b)(2) of the Food, Drug, and Cosmetic Act. Within 45 days of receipt of notice of Liquidia's NDA, United Therapeutics sued Liquidia in the District of Delaware for infringement based on U.S. Patent No. 9,593,066 ("the '066 patent") which covers its own approved NDA (No. 022387) for Tyvaso®, an inhaled solution formulation of treprostinil for the treatment of pulmonary hypertension. United Therapeutics filed another patent application that issued as U.S. Patent No. 10,716,793 ("the '793 patent") which was joined to the district court litigation. Liquidia challenged the '793 patent before the Patent Trial and Appeal Board, from which a FWD issued on July 19, 2022, invalidating all claims of the '793 patent. After a failed rehearing attempt by United Therapeutics, the IPR is on a pending appeal before the Federal Circuit as of the time of this publication. The district court subsequently decided that claims 1, 4, and 6–8 of the '793 patent are not invalid and are infringed; claims 1-3, 6, and 9 of the '066 patent are anticipated; that claims 1-3 of the '066 patent are infringed, while claims 6, 8, and 9 are not infringed. Liquidia appealed, and United Therapeutics cross-appealed the parts of the decision that were respectively disadvantageous to each party.

Issue(s)

- Whether the claim limitation "treating pulmonary hypertension" of the '793 patent includes safety and efficacy.
- Whether the '793 patent claims are enabled.
- Whether the '793 patent claims are supported by written description.
- Whether the District Court clearly erred in finding induced infringement of claims 1, 4, and 6-8 of the '793 patent.
- Whether the District Court clearly erred in finding infringement of claims 1-3 of the '066 patent.
- Whether the District Court clearly erred in finding no infringement of claims 6 and 8 of the '066 patent.
- Whether the District Court clearly erred in finding claims 1-3, 6, and 9 of the '066 patent invalid based on anticipation under §102 in view of prior art reference Moriarty.

Holding(s)

- The District Court's claim construction was correct that "treating pulmonary hypertension" as recited in the '793 patent includes treating all five groups of pulmonary hypertension patients.
- Claim limitation of "treating pulmonary hypertension" does not include the non-recited limitations of safety and efficacy.
- Claims of the '793 patent are adequately enabled.
- Claims of the '793 patent are supported by written description.
- The District Court did not clearly err in finding induced infringement because the '793 IPR decision does not affect finding of induced infringement.
- Issue of infringement of claims 1-3 of the '066 patent is rendered moot by invalidated claims.
- The District Court did not clearly err in finding claims 1-3, 6, and 9 anticipated by Moriarty.
- The District Court did not clearly err in finding claims 1-3, 6, and 9 of the '066 patent invalid.

Reasoning

As to the claim construction of pulmonary hypertension, the Federal Circuit found that the '793 specification does not limit scope of pulmonary hypertension to any specific group.

Liquidia did not challenge the claim construction of "therapeutically effective single event dose" which the District Court construed as "a dose given in a single treatment session that causes an improvement in a patient's hemodynamics."

The Federal Circuit found that read in context, the claim language of "'treating pulmonary hypertension' does not import any additional efficacy limitations or any safety limitations," and that it is wrong to partition a disease or condition to require a separate disclosure in the specification for each individual variant of the condition, unless the variants are specified in the claims.

The '793 specification describes the claimed "treating pulmonary hypertension comprising administering . . . a therapeutically effective single event dose of a formulation containing treprostinil."

The Federal Circuit noted that safety and efficacy are responsibilities of the Federal Drug Administration (FDA), not that of the Patent & Trademark Office (PTO). Thus, the FDA's responsibilities should not be inserted into claims where no such limitations are recited.

The Federal Circuit found that the district court properly relied on expert testimony and record evidence to conclude that a skilled artisan would understand that the claimed single dose administration of treprostinil would improve hemodynamics regardless of the type (i.e., group) of pulmonary hypertension patient.

As to the enablement issue, the Federal Circuit agreed with the district court's finding of enablement in the details in the '793 patent specification on administration, concentrations, dosages, and description of an open label study; and expert testimony.

The Federal Circuit reasoned that these disclosures in the record satisfy all that the claims require under the district court's construction of a "therapeutically effective single dose."

As to the issue of providing written description, the Federal Circuit agreed with the district court that noted the specification describes "treating pulmonary hypertension comprising administering . . . a therapeutically effective single event dose of a formulation containing Treprostinil." The Federal Circuit noted that the same reasons for rejecting Liquidia's claim construction arguments regarding safety and efficacy apply to this issue as well.

As to whether the FWD invalidating claims in the IPR negated the finding of induced infringement, the Federal Circuit noted that "[a] pending, non-final litigation does not negate an intent to infringe that is otherwise supported by evidence."

The Federal Circuit reasoned that:

1. An IPR decision does not have collateral estoppel effect until that decision is affirmed or the parties waive their appeal rights; and

2. The PTAB's final written decision does not cancel claims; the claims are cancelled when the Director issues a certificate confirming unpatentability.

As to the issue of invalidation by anticipation by Moriarty, the Federal Circuit stated that "a product-by-process claim is a product claim."

Prior art Moriarty discloses treprostinil of 99.7% purity which falls in the scope of the '066 specification of 99.7-99.9% purity, although it may not disclose purification through salt formation and the same level of alkylation or hydrolysis impurities as described in the specification which are not claimed.

No evidence was provided "identifying any structural or functional differences between the Moriarty treprostinil and the claimed treprostinil" of the '066 patent, and the Federal Court found the district court's reasoning well supported.

The District Court credited Liquidia's representations to the FDA that it would store treprostinil sodium between 2°C and 8°C, which falls outside of the District Court's claim construction of "ambient temperature" as room temperature between 15°C to 30°C.

The District Court found that storage between steps of Liquidia's manufacturing process did not meet the limitations of claims 8 and 9 of the '066 patent, which require storage of treprostinil before preparing a pharmaceutical product.

In Re: Cellect, LLC

Nos. 2022-1293, 2022-1294, 2022-1295, 2022-1296 (Fed. Cir. Aug. 28, 2023)

By: Zijian Han

Topic

This case addresses how Patent Term Adjustment (PTA) interacts with obviousness-type double patenting (ODP).

Background

Cellect sued Samsung Electronics, Co. for infringement of four patents. Subsequently, Samsung requested four *ex parte* reexaminations asserting that the patents were unpatentable based on ODP, which was not raised by the examiner during prosecution. In each *ex parte* reexamination, the examiner determined that the challenged claims were obvious variants of Cellect's prior-expiring reference.

Patent claims: All invalidated claims can be traced back to the single family member patent that did not receive a grant of PTA (Patent Term Adjustment): the '036 patent. Cellect appealed to Patent Trial and Appeal Board (the "Board"). Cellect noted that ODP does not invalidate a validly obtained Patent Term Extension ("PTE") and primarily argued that the Board should similarly hold that ODP cannot negate a statutory grant of PTA.

The Board framed the issue as a question of how PTA affects an ODP analysis and whether an ODP analysis should be based on the expiration date of a patent with or without any granted PTA added. The Board then held that both ODP and terminal disclaimers should be considered after any PTA, and sustained the examiner's rejection in each *ex parte* reexamination. Cellect appealed to the Federal Circuit.

Issue(s)

- Did the Board err in finding that whether claims are unpatentable for ODP is determined based on the date of expiration of a patent that includes any duly granted PTA pursuant to 35 U.S.C. § 154?

- Did the Board err in failing to consider the equitable concerns underlying the finding of ODP in the *ex parte* reexamination proceedings?

- Did the Board err in finding a substantial new question of patentability in the underlying *ex parte* reexaminations?

Holding(s)

- No. The Board did not err in finding that whether claims are unpatentable for ODP is determined based on the date of expiration of a patent that includes any duly granted PTA pursuant to 35 U.S.C. § 154.

- No. The Board did not fail to consider the equitable concerns underlying the finding of ODP in the *ex parte* reexamination proceedings.

- No. The Board did not err in finding a substantial new question of patentability in the underlying *ex parte* reexaminations.

Reasoning

The Federal Circuit agreed with the USPTO that PTA and PTE should be treated differently from each other when determining whether or not claims are unpatentable under ODP. While the expiration date used for an ODP analysis where a patent has received PTE is the expiration date before the PTE has been added, the expiration date used for an ODP analysis where a patent has received PTA is the expiration date ***after*** the PTA has been added. While PTE is designed to effectively extend the overall patent term for a single invention due to regulatory delays in product approval, PTA is designed to extend the term of a particular patent due to delays in the processing of that patent. According to the Federal Circuit, ODP is a judicially created doctrine with a purpose to prevent an inventor from securing a second, later-expiring patent for non-distinct claims. There is nothing in the PTA statute to suggest that application of ODP to the PTA-extended patent term would be contrary to the congressional design. The Federal Circuit further found that, here, the patents are related, claim overlapping subject matter, and have different expiration dates only because of PTA. Thus, ODP applies to ensure that the applicant is not receiving an unjust extension of time.

The Federal Circuit noted that terminal disclaimers are almost always filed to overcome ODP rejections. Cellect had the opportunity to file terminal disclaimers during both prosecution and *ex parte* reexaminations, but they did not. Thus, the Federal Circuit found that, in the absence of such disclaimers, it would frustrate the clear intent of Congress for applicants to benefit from their failure, or an examiner's failure, to comply with established practice concerning ODP.

The Federal Circuit found that any extension past the expiration date of the '036 patent, which did not receive a grant of PTA, constitutes an inappropriate timewise extension for the asserted claims of the challenged patents. To hold otherwise would, in effect, confer on the reference claims of the '036 patent PTA to which they were not entitled. The Federal Circuit also agreed with USPTO that the risk remains for multiple assignees to seek past damages.

The Federal Circuit found that substantial evidence supports that the reexamination requests raised a substantial new question of patentability. The Federal Circuit noted that neither party points to anything in the prosecution history that affirmatively indicates that the examiner considered whether or not an ODP rejection should be made. It further held that the threshold for showing a substantial new question was met.

Columbia Sportswear North America, Inc. v. Seirus Innovative Accessories, Inc.

Nos. 2021-2299, 2021-2338 (Fed. Cir. Sept. 15, 2023)

By: Sofya Asatryan

Topic

The Federal Circuit vacated a jury verdict of non-infringement in a design-patent infringement action filed by Columbia Sportswear against Seirus Innovative Accessories. It found that the lower court erred by failing to instruct the jury that "comparison prior art" must be tied to the same article of manufacture as that claimed.

Background

Columbia asserted U.S. Design Patent No. D657,093, which claims "[t]he ornamental design of a heat reflective material" featuring contrasting wavy lines, against Seirus based on Serius' HeatWave products. These products (e.g., gloves) have a wavy pattern with the "Seirus" logo throughout the design. Columbia obtained summary judgment of infringement against Seirus, and Seirus successfully appealed. On remand, the jury returned a verdict of non-infringement.

Columbia appealed, mainly challenging the jury instructions on comparison art (which serves as background when comparing a claimed and accused design) and jury instructions on the Seirus logo.

Regarding the jury instructions on comparison prior art, Columbia argued that the district court erred by failing to instruct the jury as to the scope of the comparison prior art. At trial, Columbia submitted draft jury instructions stating that "[t]he term 'prior art' refers to prior designs of the same article of manufacture or of articles so similar that a person of ordinary skill would look to such articles for their design." The district court refused to apply Columbia's draft instructions and instead gave instruction that the jury "must decide what is prior art." Regarding the jury instructions addressing Seirus' logo on the accused HeatWave design, Columbia argued that the district court's instructions were erroneous for not specifying (1) that consumer confusion as to source is irrelevant to design-patent infringement, or (2) that a jury need not find a likelihood of consumer confusion to find such infringement.

Issue(s)

- Whether the district court erred in its jury instructions on the comparison prior art and the Seirus logo.

Holding(s)

The Federal Circuit agreed with Columbia that the district court failed to properly instruct the jury because the jury was not provided the correct standard for determining whether an admitted reference qualified as comparison prior art. The Federal Circuit further found that the error was prejudicial and warranted vacating the non-infringement judgment and remanding for further proceedings. However, the Federal Circuit disagreed with Columbia's argument that the district court erred by not instructing that consumer confusion as to source is irrelevant for design-patent infringement, or that likelihood of confusion (in addition to actual confusion) need not be found.

Reasoning

Regarding the jury instruction on comparison prior art, the Federal Circuit stated that "the proper scope of comparison prior art that may be used in an infringement analysis is an issue of first impression." Thus, the prior-art design must be applied to the article of manufacture identified in the claim. The district court erred by failing to instruct the jury as to the scope of the asserted patent's claim (design for a heat reflective material). The Federal Circuit stated this error was an understandable one, given that the court had just now articulated this standard.

Regarding the jury instruction on Serius' logo, the Federal Circuit reasoned that the district court's provision of the ordinary-observer test for design patent infringement was materially identical to how the Supreme Court and Federal Circuit have stated it, and that the district court specified that actual confusion was not necessary to find design-patent infringement. The Federal Circuit was not convinced that the district court's decision not to include these additions or clarifications was an abuse of discretion or resulted in instructions that were misleading or incomplete. While the Federal Circuit acknowledged the potential for a jury to be led astray and mistakenly conflate the significance of a logo's source-identifying function with whatever impact it might have on a comparison of the designs, it found that district courts are in the best position to decide whether and when to provide clarification on these issues.

Finjan LLC, FKA Finjan, Inc. v. SonicWall, Inc.

No. 2022-1048 (Fed. Cir. Oct. 13, 2023)

By: Fred Chung & Eric Gill

Topic

The Federal Circuit vacated a summary judgement of invalidity based on collateral estoppel, where the case that provided estoppel was subsequently vacated. The Federal Circuit also examined various arguments attempting to circumvent an agreed-upon claim construction as well as the district court's application of that construction in finding non-infringement, and the propriety of excluding expert testimony that failed to analyze apportionment of sub-features of the accused products.

Background

Finjan asserted U.S. Patent Nos. 8,677,494 ("'494 patent"), 6,154,844 ("'844 patent"), 6,804,780 ("'780 patent"), and 7,613,926 ("'926 patent") (together "Downloadable Patents") and 8,225,408 ("'408 patent," "ARB Patent") in the Northern District of California, alleging that SonicWall infringed the patents based on its Gateway, Email Security ("ES"), and Capture Advanced Threat Protection ("ATP") products. The district court granted SonicWall's motion for summary judgment regarding invalidity of the '844, '780, and '494 based on indefiniteness, due to collateral estoppel—the '844 and '780 patents had been found invalid for indefiniteness in a prior case Finjan brought against ESET, LLC in the Southern District of California. After the district court granted SonicWall's summary judgment motion, in Finjan's appeal of the indefiniteness finding in the ESET case, the Federal Circuit vacated and remanded the indefiniteness finding. *Finjan LLC v. ESET, LLC*, 51 F.4th 1377, 1378–79 (Fed. Cir. 2022). In addition to summary judgment of invalidity, the district court in Finjan's case against SonicWall granted summary judgement of non-infringement for the Downloadable Patents based on the agreed construction of "downloadable" as "an executable application program, which is downloaded from a source computer and run on the destination computer" and Finjan's failure to present evidence that SonicWall's Gateway products ever reassembles packets into a final executable file format. The district court also found SonicWall did not infringe the ARB Patent because the district court agreed with SonicWall that the claimed steps must be performed on the same computer and there was no dispute that the Capture ATP products run on separate computers from the Gateway and ES products. The district court also excluded expert testimony related to apportionment in Finjan's technical and damages reports. Finjan appealed.

Issue(s)

- Whether collateral estoppel applies to a judgement of invalidity when the prior case has been vacated.
- Whether receiving packets that contain a downloadable or portions thereof constitutes receiving a downloadable.
- Whether claim limitations carried out "by ***the*** computer," where "the computer" refers to a previous recitation of "by ***a*** computer," can cover different steps performed by multiple computers.
- Whether Finjan's apportionment analysis was proper, when the Federal Circuit previously approved a purportedly mirrored analysis in *Finjan, Inc. v. Blue Coat Systems, Inc.*, 879 F.3d 1299, 1312–13 (Fed. Cir. 2018).

Holding(s)

The Federal Circuit vacated the district's court's summary judgment ruling that the '844, '780, and '494 patents are invalid based on collateral estoppel.

The Federal Circuit affirmed summary judgement of non-infringement of the Downloadable Patents.

The Federal Circuit affirmed summary judgement of non-infringement of the ARB Patent.

The Federal Circuit affirmed the district court's exclusion of expert testimony relating to apportionment.

Reasoning

Collateral estoppel. The Federal Circuit stated that it "cannot uphold applying collateral estoppel based on a vacated judgment," citing 9th Circuit precedent as guidance.

Non-infringement of the Downloadable Patents. The district court's finding flowed from the parties' agreed-upon construction and parties are not permitted to raise claim construction arguments on appeal challenging a stipulated construction. Therefore, the Federal Circuit focused on whether the district court properly analyzed infringement under the agreed-upon construction. The Federal Circuit rejected Finjan's arguments on appeal because the district court's application of the agreed construction did not exclude preferred embodiments and comported with the claim language, including dependent claims, and specifications, and because Finjan's arguments otherwise "failed to grapple with the parties' agreed upon construction and testimony from Finjan's own expert." 2022-1048, Dkt 45 (slip op.) at 14. Ultimately, the Federal Circuit rejected Finjan's various arguments because they failed to address the crux of the district court's reasoning, which was based on the fact that an unassembled packet containing a downloadable is not executable. Therefore, the Federal Circuit affirmed.

Non-infringement of the ARB Patent. The Federal Circuit also affirmed the district court's finding that because the '408 patent's claims recite a step performed by "a computer" and subsequent steps require performance by "the" computer, the claims "require the same computer to perform each of several subsequent claim limitations." *Id.* at 20. The Federal Circuit likened the claims in this case to those in *Salazar v. AT&T Mobility LLC*, 64 F.4th 1311, 1317 (Fed. Cir. 2023) and *Traxcell Techs., LLC v. Nokia Sols. & Networks Oy*, 15 F.4th 1136, 1143–44 (Fed. Cir. 2021), where subsequent limitations required that the claim element forming antecedent basis be capable of performing each claimed function. The Federal Circuit noted no tension between the holdings in *Salazar* and *Nokia* and the cases Finjan cited—*Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338 (Fed. Cir. 2008) and *01 Communique Laboratory, Inc. v. LogMeIn, Inc.*, 687 F.3d 1292 (Fed. Cir. 2012)—because *Baldwin* and *Communique* did "not address[] whether the use of a definite article to refer to the initial antecedent phrase requires the same component to perform the later limitation." The Federal Circuit also noted that Finjan did not challenge the district court's reasons for denying Finjan's motion for reconsideration of the summary judgement of non-infringement of the ARB Patent: that Finjan did not show that a single computer satisfies the relevant limitations with its argument that the accused products together operate "as unified computer systems"; and that Finjan did not show a manifest failure of the district court to consider Finjan's legal arguments.

Exclusion of expert testimony. The Federal Circuit found that the district court did not abuse its discretion in excluding Finjan's expert's apportionment analysis where the expert failed to consider how SonicWall's customers derived value solely from the sub-features of the accused products allegedly covered by the ARB Patent," or to non-accused or non-patented functions of the accused products. The Federal Circuit agreed that Finjan's expert fatally failed to carefully tie his analysis to allegedly infringing features and to exclude value attributable to unpatented features. Finjan's reliance on *Blue Coat* was misplaced because the Federal Circuit "held [in *Blue Coat*]—as [it did] here—that Finjan's expert failed to apportion the value of unpatented elements from patented elements." *Blue Coat* is distinguishable because (1) the issue in *Blue Coat* was whether a jury's damages award was supported by substantial evidence, rather than a district court's abuse of discretion for striking expert testimony pre-trial, which is the issue here; and (2) *Blue Coat*, unlike the case here, did not involve sub-features. 2022-1048, Dkt 45 at 23.

Cyntec Company, Ltd. v. Chilisin Electronics Corp., Chilisin America Ltd.

Nos. 2022-1873, (Fed. Cir. Oct. 16, 2023)

By: Don Geiger & Eric Gill

Topic

This case is primarily about the *Daubert* standard as applied to expert testimony on damages. The Federal Circuit reversed the Northern District of California's admission of expert testimony on damages, which relied on calculations that failed to differentiate between infringing products and non-infringing products. The Federal Circuit also reiterated the standards for a judgment as a matter of law ("JMOL") of non-obviousness, and clarified that "by means of" claim language does not limit to but-for causation, *i.e.*, it does not mean "by *the exclusive* means of."

Background

Cyntec Company, Ltd. ("Cyntec") owns patents directed to electronic components for automobiles known as chokes. Chokes are generally fabricated by wrapping a magnetic core with insulated wire. Prior art chokes were molded by annealing a mixture of magnetic powder and adhesive around the insulated wire. This molding process could heat the wire insulation to its melting point and damage the choke. Cyntec's patents sought to solve this issue by claiming chokes with a combination of two different magnetic powders. The grains of the first powder are harder and larger than the grains of the second powder. According to Cyntec, using this type of two-powder configuration improves the performance of the magnetic core and allows the molding process to anneal the mixture at lower temperatures, resulting in fewer incidents of melted wire insulation, and lowers the probability of damaging the chokes.

The Federal Circuit cited the following claim as representative:

An electronic device, comprising:

- a first magnetic powder;
- a second magnetic powder, wherein the mean particle diameter of the first magnetic powder is larger than the mean particle diameter of the second magnetic powder, the Vicker's Hardness of the first magnetic powder is greater than the Vicker's Hardness of the second magnetic powder by a first hardness difference, and the first magnetic powder mixes with the second magnetic powder; and
- a conducting wire buried in the mixture of the first magnetic powder and the second magnetic powder, wherein the conducting wire comprises an insulating encapsulant and a conducting metal encapsulated by the insulating encapsulant;
- wherein by means of the first hardness difference of the first magnetic powder and the second magnetic powder, the mixture of the first magnetic powder and the second magnetic powder and the conducting wire buried therein are combined to form an integral magnetic body at a temperature lower than the melting point of the insulating encapsulant.

Cyntec sued Chilisin Electronics Corp. ("Chilisin") for patent infringement, alleging that Chilisin willfully manufactured and sold infringing chokes.

Chilisin argued that the "by means of" language in the last claim limitation requires the difference in powder grain hardness be *the sole reason* for the lowered annealing temperature. The district court rejected this construction and eventually instructed the jury that the "by means of" language requires only that the difference in powder grain hardness *contribute* to the lowered annealing temperature.

Before trial, Chilisin moved to exclude the testimony of Cyntec's damages expert, arguing that the expert's calculations relating to the importation of accused products sold by Chilisin were speculative and unreliable. But the court allowed the testimony because "[the expert's] opinions rely on data sources that are sufficiently reliable that a jury can determine whether the assumptions made in his calculations were valid."

At trial, Chilisin presented evidence to the jury on invalidity and Cyntec presented expert testimony in rebuttal. Cyntec moved for JMOL of nonobviousness before Chilisin could cross-examine Cyntec's expert, and the district court granted Cyntec's motion. The district court agreed with Cyntec that the cited prior art combination was missing claim elements and that Chilisin failed to meet the clear and convincing standard regarding motivation to combine.

To prove damages at trial, Cyntec presented a market-share lost profits theory, alleging that 27 companies purchased Chilisin's accused chokes outside the United

States and then imported devices including the chokes into the United States. Cyntec's expert calculated $1,552,493 in lost profits and $320,463 in reasonable royalties. The jury awarded Cyntec the full amount and also found that Chilisin willfully infringed the patents. After denying Chilisin's motion for a new trial, the court granted Cyntec's motion for enhanced damages, resulting in a total lost profits award of $4,602,671 and reasonable royalties award of $950,573.

Chilisin then appealed to the Federal Circuit.

Issue(s)

- Did the district court err in granting Cyntec's JMOL of non-obviousness before underlying factual disputes were given to the jury?
- Was the court's construction of the "by means of" claim term erroneous?
- Was there substantial evidence to support the jury's finding of infringement?
- Did the district court err in denying Chilisin's motion to exclude Cyntec's expert testimony on damages under *Daubert*, where such testimony was based on an unsupported assumption that sales revenue for purchasing companies' products *as a whole* reflected sales of infringing products they had purchased from Chilisin?

Holding(s)

The district court erred in granting Cyntec's JMOL of non-obviousness before factual disputes were given to the jury. The JMOL for non-obviousness was reversed and remanded.

The court's construction of the "by means of" claim term was not erroneous. The plain language of the "by means of" limitation requires only that the difference in powder grain hardness contribute to the lowered annealing temperature.

There was substantial evidence to support the jury's finding of infringement. The judgment of infringement was affirmed.

The district court abused its discretion in admitting Cyntec's unreliable expert testimony on damages. The district court's denial was reversed and the damages award is vacated.

Reasoning

Regarding the NDCA's erroneous granting of JMOL of non-obviousness: Factual underpinnings of non-obviousness, *e.g.*, the *Graham* factors for obviousness and a POSITA's motivation to combine prior art references, are issues of fact ordinarily for the jury. These factual issues may be excluded from the jury by JMOL of non-obviousness where, after viewing all the evidence and reasonable inferences in light of the non-moving party, no reasonable juror could find the asserted claims obvious.

The Federal Circuit held that Chilisin presented evidence sufficient for a reasonable juror to find the asserted claims obvious. Chilisin presented a first prior art reference disclosing chokes comprising a two-powder configuration and a second prior art reference disclosing electronic devices with two-powder configurations having one powder larger and harder grained than the other. Chilisin also presented expert testimony that a POSITA would be motivated to combine the two prior art references to improve the permeability of the magnetic core in the first prior art reference.

Regarding the NDCA's construction of the "by means of" claim term: The Federal Circuit acknowledged that "by means of" is broad enough to include but-for causation, but pointed out that it is also broad enough to include mere contribution. Further, if the patentee had intended to limit to the difference in powder grain hardness being the *sole* reason for the reduction in annealing temperature, the patentee would have either indicated as much in the spec or used more explicit language, *e.g.*, "by exclusive (or primary) means of."

Regarding whether there was substantial evidence for the jury's finding of infringement: Cyntec presented expert testimony explaining how the differences in hardness and size between the constituent powder grains affected the annealing temperatures. Cyntec also presented testimony from its vice-president that these differences affected the accused product's reliability. The Federal Circuit concluded this was enough for a juror to reasonably reach its infringement finding given the plain meaning of the "by means of" limitation discussed above.

Regarding the exclusion of Cyntec's expert testimony on damages: The Federal Circuit cited two precedential cases regarding excluding unreliable damages expert testimony. In the first case, *Power Integrations v. Fairchild Semiconductor International, Inc.*, 711 F.3d 1348, 1357 (Fed. Cir. 2013),

the Federal Circuit threw out expert testimony on damages because it relied on calculations that assumed, without evidence, that all shipments of certain mobile phones included an infringing power circuit, even though the power circuits were found in chargers and not phones. Similarly, in the second case, *Niazi Licensing Corporation v. St. Jude Medical S.C., Inc.*, 30 F.4th 1339, 1343–44 (Fed. Cir. 2022), the Federal Circuit threw out expert testimony on damages because it relied on calculations that included all of the defendant's sales of catheters and related components, even though it was undisputed that not all of the catheters and components practiced the claimed method.

Here, Cyntec's expert calculated an "importation rate" for each of 27 companies that allegedly bought infringing products from Chilisin. Cyntec's expert calculated this importation rate based on the purchasing company's United States revenue divided by its worldwide revenue. Cyntec's expert then multiplied the importation rate for a given purchasing company by Chilisin's revenue collected outside the United States from that purchasing company to determine the infringement revenue subject to damages. Cyntec's expert treated the result of these calculations as Chilisin's revenue for indirect sales to the United States via that purchasing company. He then applied Cyntec's market share to this revenue to yield an estimate of Cyntec's lost sales.

The Federal Circuit held that the district court's denial of Chilisin's *Daubert* motion—based on the court's finding that Cyntec's expert's opinions relied on data sources that are sufficiently reliable that a jury can determine whether the assumptions made were valid—was an abuse of discretion. The expert's calculations assumed, without evidence, that the sales revenue for the purchasing companies' products as a whole reflected sales of infringing products they had purchased from Chilisin. Like the flawed calculations in *Power Integrations* and *Niazi Licensing*, the expert's testimony here relied on data that failed to differentiate between infringing products and non-infringing products. The Federal Circuit found the expert's opinion was derived from unreliable data and built on speculation and, therefore, the district court abused its discretion when it allowed the expert's opinion.

Allgenesis Biotherapeutics Inc. v. Cloudbreak Therapeutics, LLC

No. 2022-1706 (Fed. Cir. Nov. 7, 2023)

By: Samantha Young

Topic

This case addresses whether an IPR petitioner can assert Article III standing on appeal based on potential infringement liability and potential preclusive effects on its patents.

Background

Cloudbreak owns U.S. Patent No. 10,149,820 (the "'820 patent"), which is directed to compositions and methods for treating pterygium. Allgenesis petitioned for *inter partes* review of all claims of the '820 patent. The Patent Trial and Appeal Board ("PTAB" or "Board") found that Allgenesis failed to show that Allgenesis' PCT application anticipated claims 4 and 5 of the '820 patent. The Board found that claims 4 and 5 of the '820 patent were entitled to the priority date of the corresponding provisional application, which predated the PCT application. On appeal, Allgenesis argued that the PTAB erred in attributing the provisional's priority date to the claims. Additionally, the PTAB determined that Allgenesis failed to show that claims 4 and 5 were obvious over multiple references because the claims were directed to unexpected results. On appeal, Allgenesis argued that the PTAB erred in determining that claims 4 and 5 were directed to unexpected results. However, despite Allgenesis' issues on appeal, the Federal Circuit only addressed whether Allgenesis had standing to bring an appeal.

Issue(s)

- Does Allgenesis have standing under Article III to seek review of the PTAB's decision?

Holding(s)

Allgenesis does not have standing under Article III because it failed to establish an injury in fact.

Reasoning

While the Federal Circuit has jurisdiction to review final decisions of the Board, Article III of the U.S. Constitution limits jurisdiction to the adjudication of

cases and controversies. Although a party does not need Article III standing to file an IPR petition, the party still requires Article III standing to seek review of the Board's decision in the Federal Circuit. In particular, a party must show that it suffered an injury in fact. Allgenesis argued that it suffered an injury in fact based on the potential infringement liability stemming from its development of nintedanib treatments for pterygium. The Federal Circuit determined that Allgenesis failed to show that it has concrete plans for future activity that creates a substantial risk of future infringement or may cause the patentee to assert a claim of infringement. While Allgenesis submitted declarations asserting potential infringement liability, the declaration did not identify any of Allgenesis' recent development activities or its plans for future clinical development. Furthermore, the Federal Circuit found the declaration was conclusory and failed to establish that Allgenesis had any concrete plans to develop and bring to market a nintedanib treatment for pterygium. Allgenesis also asserted settlement conversations as evidence of a likelihood of litigation for patent infringement when Allgenesis brings its product to market. The Federal Circuit found that this evidence was insufficient since Allgenesis did not make any assertions that Cloudbreak has sued or threatened to sue Allgenesis if it brings a nintedanib product to market. Accordingly, the Federal Circuit concluded that Allgenesis failed to show an injury in fact based on potential infringement liability.

Allgenesis also argued it suffered an injury in fact based on the Board's priority determination. In particular, Allgenesis asserted that the Board's relative priority determination affects the scope Allgenesis' own patent rights because the PCT application and the '820 patent are directed to the same invention. Allgenesis also asserted it suffered an injury in fact because the Board's determination will have a preclusive effect on the scope of its pending patent application claiming priority to the PCT application. However, the Federal Circuit rejected this argument and determined that Allgenesis did not establish that the Board's decision will have preclusive effect. The Federal Circuit relied on *Best Medical International, Inc. v. Elekta Inc.*, 46 F.4th 1346 (Fed. Cir. 0222) to assert that collateral estoppel will not attach to the Board's non-appealable priority determination. Additionally, the Federal Circuit determined that Allgenesis failed to articulate with any specificity how the Board's priority determination will impact its issued patents or pending continuation applications which claim priority to its PCT application. The Federal Circuit concluded that Allgenesis' general and nonspecific allegations were insufficient to meet its burden of establishing standing.

Purdue Pharma L.P. v. Collegium Pharmaceutical, Inc.

No. 2022-1482 (Fed. Cir. Nov. 21, 2023)

By: Theo Mayer

Topic

This case addresses the Patent Trial and Appeal Board's ("PTAB's") authority to issue a Final Written Decision in a post grant review ("PGR") after the prescribed statutory deadline.

Background

In September 2017, Purdue Pharma L.P. ("Purdue") sued Collegium Pharmaceutical, Inc. ("Collegium") for infringement of US Pat. No. 9,693,961 ("the '961 patent").

In March 2018, Collegium petitioned the PTAB for PGR of claims 1-17 of the

'961 patent. Based on a finding that the challenged claims lacked sufficient written description, the PTAB instituted PGR in October 2018. Under 35 U.S.C. § 326(a)(11) and 37 C.F.R. § 42.200(c), the PTAB had one year to issue a Final Written Decision, subject to a six month extension for "good cause." The one year deadline fell on October 4, 2019.

In September 2019, Purdue filed a Notice of Bankruptcy Filing and Imposition of Automatic Stay. The PTAB subsequently stayed the PGR.

Two days before the one year deadline for the PTAB's Final Written Decision in the PGR, the Chief Administrative Patent Judge found good cause to grant a six month extension so the bankruptcy court could assess whether the automatic stay applied to PGRs. Neither party sought guidance from the bankruptcy court nor asked the bankruptcy court to lift the stay during the six-month extension period.

On April 4, 2020, the extended deadline for the PTAB's Final Written Decision in the PGR passed.

On September 1, 2020, the bankruptcy court lifted the automatic stay of the PGR.

On September 11, 2020, Purdue filed a motion to terminate the PGR, arguing the PTAB no longer had the authority to issue a Final Written Decision as the statutorily prescribed 18-month deadline had passed.

On November 19, 2021 (approximately 19 months after the statutory deadline as extended), the PTAB denied Purdue's motion and issued its Final Written Decision, finding the challenged claims unpatentable for lack of written description and as anticipated by the prior art.

Purdue appealed the PTAB's Final Written Decision to the Federal Circuit.

Issue(s)

- Did the PTAB have authority to issue a Final Written Decision in the PGR after the prescribed statutory deadline?

Holding(s)

The PTAB had authority to issue a Final Written Decision in the PGR after the prescribed statutory deadline because 35 U.S.C. § 326(a)(11) (i.e., the applicable statutory deadline provision) does not specify any consequences for missing the deadline and Supreme Court precedent dictates that "if a statute does not specify a consequence for non-compliance with statutory timing provisions, the federal courts will not in the ordinary course impose their own coercive sanction." *United States v. James Daniel Good Real Prop.*, 510 U.S. 43, 63 (1993).

Reasoning

Reasoning focused on the precedential issue of whether the PTAB has authority to issue a Final Written Decision in a PGR after the prescribed statutory deadline.

The Federal Circuit noted that this PGR presented the first instance where the PTAB failed to meet the deadline prescribed in 35 U.S.C. § 326(a)(11) – rendering this a matter of first impression.

The Federal Circuit first determined that 35 U.S.C. § 326(a)(11) does not specify any consequences for missing the deadline.

In *United States v. James Daniel Good Real Prop.*, the Supreme Court held that "if a statute does not specify a consequence for non-compliance with statutory timing provisions, the federal courts will not in the ordinary course impose their own coercive sanction." 510 U.S. 43, 63 (1993). Applying this rule in *Liesegang v. Sec'y of Veterans Affs*, the Federal Circuit later held that "even in the face of a statutory timing directive, when a statute does not specify the consequences of non-compliance, courts should not assume that Congress intended that the agency lose its power to act." 312 F.3d 1368, 1376–77 (Fed. Cir. 2002)).

Following the above precedent in this case, the Federal Circuit determined "the [PTAB] has authority to issue a Final Written Decision even after the deadline proscribed in the statute has passed absent any contrary indication in the language, structure, or legislative history of the statute."

Regarding the statute's language and structure, the Federal Circuit determined:

- consistent with the Supreme Court's decision in *Brock v. Pierce Cnty.*, 476 U.S. 253, 266 (1986), the use of "shall" and "requirement" in 35 U.S.C. § 326(a)(11) (i.e., "Director ***shall*** prescribe regulations– . . . ***requiring*** that the final determination in any post-grant review be issued not later than 1 year") does not deprive the PTAB of authority to issue a Final Written Decision after the deadline;
- consistent with *Liesegang* the negative words of "not later than 1 year" and "by not more than 6 months" in 35 U.S.C. § 326(a)(11) "are at best precatory rather than mandatory" – and thus such language does not deprive the PTAB of authority to issue a Final Written Decision after the deadline;
- the mere mention that PGRs shall be conducted "in accordance" with section 6 of 35 U.S.C. Section 326(c) or that PGRs be conducted "pursuant to" chapter 32 does not rise to the level of a clear statement that section 326(a)(11) is jurisdictional – and thus such language does not deprive the PTAB of authority to issue a Final Written Decision after the deadline;
- consistent with *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 159 (2003), the exceptions in 35 U.S.C. § 326(a)(11) for "good cause" and "joinder" do not strip the PTAB of authority to issue a Final Written Decision after the deadline passed; and
- the mandate that the PTAB issue a Final Written Decision prescribed 35 U.S.C. § 328(a) demonstrates that "[h]ad Congress meant to deprive the agency of power in section 326(a)(11), it knew how to do it, and, significantly, it did not use language in section 326(a)(11) similar to that used in other sections."

Regarding legislative history, the Federal Circuit noted that the AIA provided for PGRs "designed to allow parties to challenge a granted patent through a[n] expeditious and less costly alternative to litigation." Introduction of Patent Reform Act, 153 Cong. Rec. E774 (Apr. 18, 2007). The Federal Circuit then determined that "forbidding the [PTAB] to issue a Final Written Decision after the deadline has passed would go against Congressional intent" of providing an expeditious and less costly alternative to litigation because "[i]f the Board could not issue a Final Written Decision, the parties would be forced to pursue the issue in district court litigation."

Nonetheless, the Federal Circuit noted that the PTAB "may not ignore statutory deadlines" and that the "appropriate remedy" for the parties would have been mandamus to compel a decision from the PTAB by the deadline. Notably, neither party sought this remedy.

VLSI Technology LLC v. Intel Corporation

No. 2022-1906 (Fed. Cir. Dec. 4, 2023)

By: Don Geiger

Topic

This case addresses various issues from VLSI's trial victory over Intel in which a jury awarded 2.1 billion in damages to VLSI, with the primary issue on appeal being the district court's denial of Intel's licensing defense.

Issue(s)

The Federal Circuit considered several issues on appeal:

- Whether substantial evidence supported that Intel literally infringed the '373 patent?
- Whether substantial evidence supported that Intel infringed the '759 patent under the doctrine of equivalents?
- Whether the district court abused its discretion by denying Intel's challenge that VLSI's damages expert departed from an economically sound methodology?
- Whether the district court abused its discretion by denying Intel's late-addition of a licensing defense?

Holding(s) and Reasoning

Substantial evidence supported the Jury's verdict that Intel literally infringed the '373 patent.

- The Federal Circuit dispensed with Intel's arguments with respect to infringement of the '373 patent in relatively short order. Citing to both expert testimony and internal Intel documents, the Federal Circuit explained that there is substantial evidence for the jury to have found that Intel's RING_RETENTION_VOLTAGE is the minimum operating voltage of the C6 SRAM, and thus Intel's accused products infringe the '373 patent.

Intel also argued that the claims of the '373 patent require that falling below the minimum operating voltage be the causal trigger for switching from one voltage source to another. However, the Federal Circuit noted that this is an argument for claim construction, and when a claim phrase is not construed, a court may defer to the jury's view of the claim phrase unless that view is contrary to the evidence presented. Finding no such contrary evidence presented by Intel and adequate support by VLSI's expert to support the jury's findings, substantial evidence existed to support the jury's verdict of infringement.

VLSI's evidence supporting its theory of infringement under the doctrine of equivalents fails as a matter of law.

- Intel argued that VLSI's evidence with respect to the doctrine of equivalents was legally insufficient to find infringement of the '759 patent. The doctrine of equivalents expands the scope of liability for infringement where an accused product falls outside the literal scope of the claim elements, but nonetheless matches the function, way, and result of the asserted claim limitations. That is, where there are insubstantial differences between the accused product and the asserted claim, a finding of infringement under the doctrine of equivalents may be proper.

- The '759 patent claims a "first master device" that sends a "request to change clock frequency" to a "programmable clock controller." The Federal Circuit explained that in order for the doctrine of equivalents to apply, VLSI had to show that Intel's accused product, "the core and certain code which resides on the power control unit, together perform substantially the same function, in substantially the same way, to achieve substantially the same result as the claimed 'first master device' and that certain other instructions on the same power control unit perform substantially the same function, in substantially the same way, to achieve substantially the same result as the claimed 'programable clock controller.'"

- However, VLSI's expert testimony on the issue did not contain any "meaningful explanation of why the way in which the request is made by Intel's accused products is substantially the same as what the claim prescribes." It is not enough for VLSI's expert to chalk up any difference between the accused product and the asserted claim to a simple "design choice." As explained by the Federal circuit, "[t]hat label does not indicate whether, or begin to explain why, the options in the choice are substantially different or substantially the same." Here, the Federal Circuit is looking for particularized evidence "linking arguments as to the insubstantiality of the differences between the claimed invention and the accused device." Finding none, the Federal Circuit found that VLSI's doctrine of equivalents theory failed as a matter of law.

The district court abused its discretion by denying Intel's challenge that VLSI's damages expert departed from an economically sound methodology.

- VLSI's damages expert undertook a reasonable royalty analysis based on a hypothetical negotiation which took into consideration the incremental technical benefit attributable to Intel's infringement, i.e., the value proposition of VLSI's technology. However, in calculating the power savings results attributable to the asserted patents–the alleged technical benefit–VLSI's expert included products that did not use the infringing functionality of the asserted patents. The Federal Circuit reasoned that such an error could not be considered harmless with respect to the damages calculation and remanded the damages case back to the district court for further adjudication.

The district court abused its discretion by denying Intel's motion for leave to amend to add a license defense.

- The district court denied Intel's motion for leave to amend based on untimeliness of the motion, prejudice to VLSI of allowing the amendment, and futility of the proposed defense. With respect to timeliness, the Federal Circuit reasoned that a delay of approximately three months between the time Fortress acquired Finjan and the time Intel filed its motion for leave to amend was not sufficient undue delay to require denial of the motion, particularly in light of Intel's diligence in complying with the notice requirements of the license.

- Similarly, with respect to prejudice, the Federal Circuit found no basis on which prejudice alone could support denial of the motion for leave to amend. For example, the district court did not explain how or why having a district court judgment sooner rather than later could help VLSI secure licenses. Without a meaningful explanation of the prejudice to VLSI of allowing amendment, or why denying the motion would not prejudice Intel, the district court abused its discretion in denying the motion for leave to amend predicated on prejudice.

- Finally, while the district court found that the license defense was untenable under Delaware law (the applicable law under the choice of law provision in the license agreement), the Federal Circuit noted that Delaware case law does not present a sufficiently clear answer to the issue of whether Intel falls under the license, particularly based on the limited analysis of the issue provided in the briefings on the motion for leave to amend. Based on that limited analysis, and the district court's misinterpretation of Delaware law, the Federal Circuit held that it was error to deny the motion to add the license defense to the case.

H. Lundbeck A/S, et al. v. Lupin Ltd., et al.

Nos. 2022-1194, 2022-1208, and 2022-1246 (Fed. Cir. Dec. 7, 2023)

By: Fred Chung, Bradley Graveline & James Hurt

Topic

In this case, the Federal Circuit held that generic pharmaceutical companies may continue to use skinny labels to avoid infringement of method of treatment claims as long as they do not engage in advertising or promotional activities that encourage infringement of the patents.

This case affirms settled law that had become somewhat uncertain due to the Federal Circuit's 2021 *Glaxo* opinion. The Federal Circuit explicitly limited its holding in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320, 1333 (Fed. Cir. 2021) to situations in which a generic pharmaceutical company engages in advertising or promotional activities for an infringing use. In the absence of such advertising or promotional activities, 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii") allows carving out infringing uses from generic labels.

Background

A number of generic pharmaceutical companies (collectively, "Defendants") filed Abbreviated New Drug Applications ("ANDAs") to market generic versions of the Trintellix® antidepressant. The approved NDA is held by Takeda Pharmaceuticals U.S.A., Inc.

Plaintiffs (H. Lundbeck A/S, Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals America, Inc.) sued to enjoin Defendants from marketing generic versions on the basis of inducing and/or contributorily infringing various patents, including U.S. Patent Nos. 9,278,096 (the "'096 patent") and 9,125,910 (the "'910 patent"). The '096 patent claims using vortioxetine (the active ingredient in Trintellix®) in patients who have previously taken certain other antidepressants and had to cease due to sexually related adverse events ("TESD" or "Treatment Emergent Sexual Dysfunction"). The '910 patent claims using vortioxetine to treat cognitive impairment.

Plaintiffs appealed the district court's determination that defendants' ANDAs did not infringe either patent following a bench trial. Some of the defendants conditionally cross appealed the district court's judgment that the two patents are not invalid. Additionally, Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") cross appealed the district court's finding that their ANDA infringes Plaintiff's U.S. Patent No. 9,101,626 (the "'626 patent") that covers a process for making vortioxetine.

Issue(s)

- Whether section 271(e)(2)(A) of the Hatch-Waxman Act creates a separate cause of action that does not require a showing of direct, induced, or contributory infringement by the ANDA filer.

- Whether infringement can be found because clinicians will allegedly prescribe the generic medication for uses claimed in the '096 and '910 patents.

Holding(s)

Judgment of non-infringement by all defendants of the '096 and '910 patents was upheld.

Judgment of infringement by Lupin of claim 12 of the '626 patent was upheld.

Reasoning

The Federal Circuit stated that precedent, including *Warner-Lambert* and its progeny, established that "'the use . . . claimed in a patent' under section 271(e)(2)(A) must be the use for which an applicant is seeking marketing approval" in order to find infringement. *Lundbeck v. Lupin* at 12.

The Federal Circuit distinguished this case from *Glaxo*. *Id.* at 14. In *Glaxo*, the Court found infringement even though Teva submitted a section viii carve out statement, on the ground that Teva used marketing and promotional materials to advertise infringing uses of its generic drug. *Id.* In contrast, in the present case the Court found that "plaintiffs' inducement case relied solely on Defendants' proposed ANDA labels as the inducing conduct. … [P] laintiffs did not identify any advertising or promotional materials that encouraged infringement." *Id.* The Federal Circuit concluded that, "it cannot be, as plaintiffs' suggest, that a patentee can bar the sale of a drug for a use covered only by patents that will have expired simply by securing a new patent for an additional, narrower use." *Id.*

Here, the labels described only one indication—the treatment of Major Depressive Disorder ("MDD") in adults. The Federal Circuit noted that Defendants' ANDA labels carved out "the superiority data in the clinical studies portion of the label and the cross-reference to that data" without "even referenc[ing] the patient class recited" in claim 7 of the '096 patent. *Id.* at 16-17. Thus, the generic labels carved out, pursuant to section viii with FDA approval, the TESD and cognitive impairment indications that are covered by the '096 and '910 patents.

The Court rejected Plaintiffs' contributory infringement claim based on knowledge of possible infringement. Plaintiff's argument defies the purpose of the Hatch-Waxman Act to allow "the sale of drugs for unpatented uses even though those sales result in some infringing uses" and the "additional requirement that there be no substantial non-infringing use" in order to find infringement. *Id.* at 18.

The Federal Circuit further found that the district court did not err in relying on evidence about recommended doses in addition to evidence that applies to all doses to find no contributory infringement under 35 U.S.C. § 271(c). *Id.* at 18-19. Additionally, the Federal Circuit found no error in the district court's reliance on "the existence of substantial non-infringing uses to find no contributory infringement." *Id.* at 20, 19-21.

Finally, the Federal Circuit affirmed the district court's construction of "reacting" due to a lack of intrinsic evidence supporting Lupin's narrow proposed construction to affirm the finding of infringement of the '626 patent.

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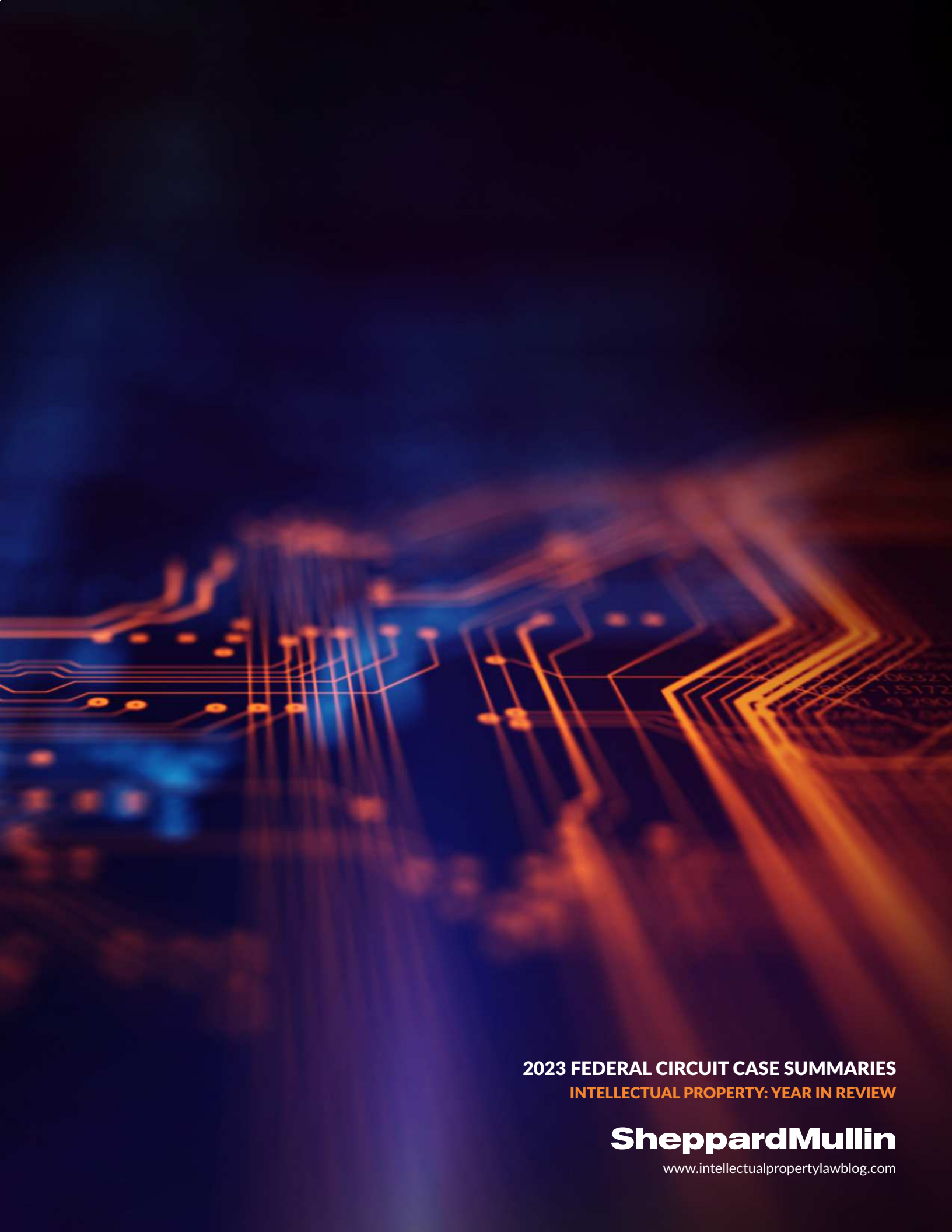

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