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Abbreviations

ALJ Administrative Law Judge

ANDA Abbreviated New Drug Application
APA Administrative Procedures Act
APJ Administrative Patent Judge

Board of Patent Appeals and Interferences

Commissioner of Patents and Trademarks

CIP Continuation-in-Part
DJ Declaratory Judgment
DOE Doctrine of Equivalents
FDA Food and Drug Administration

IDS Information Disclosure Statement
ITC International Trade Commission
JMOL Judgment as a Matter of Law

MPEP Manual of Patent Examining Procedure

NDA New Drug Application
PCT Patent Cooperation Treaty

PTO United States Patent and Trademark Office

SJ Summary Judgment

TTAB Trademark Trial and Appeal Board

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Device Merely Capable of Infringement with Alteration Does Not Necessarily Infringe

Andrew C. Michaels

Judges: Rader, Prost (author), Reyna [Appealed from S.D. Tex., Judge Hughes]

In Accent Packaging, Inc. v. Leggett & Platt, Inc., No. 12-1011 (Fed. Cir. Feb. 4, 2013), the Federal Circuit held that the district court erred in its construction of the claim terms "each" and "a respective one," reversing-in-part the district court's grant of SJ of noninfringement and remanding for entry of SJ of infringement with respect to certain claims. The Court also affirmed the district court's denial of Accent Packaging, Inc.'s ("Accent") motion for additional discovery pursuant to Fed. R. Civ. P. 56(d) and the district court's dismissal of a Missouri Uniform Trade Secrets Act ("MUTSA") cause of action for failure to state a claim.

U.S. Patent Nos. 7,373,877 ("the '877 patent") and 7,412,992 ("the '992 patent") are assigned to Accent, and are directed to a wire tier device that is used to bale recyclables or solid waste for easier handling. Accent sued Leggett & Platt, Inc. ("Leggett") on April 26, 2010, asserting infringement of claims 1-5 of the '877 patent, and claims 1, 3, 4, 7, and 10-14 of the '992 patent, as well as a claim for violation of the MUTSA, based on Leggett's alleged improper acquisition and copying of a "470 device."

Claims 1-5 of the '877 patent recite "elongated operator bodies, with *each* of the operator bodies being operably coupled with *a respective one* of said gripper, knotter, cutting element and cover" (emphases added). The district court concluded that this language required four "elongated operator bodies," since "each" must be coupled to "a respective one" of the four specified items, i.e., the gripper, knotter, cutting element, and cover. Because Leggett's accused "Pinnacle" device had only two elongated operator bodies, the district court granted SJ of noninfringement.

"'The fact that it is possible' to alter the Pinnacle so that the cover can be pivoted through a ninety degree arc 'is not enough, by itself, to justify a finding that the manufacture and sale' of the Pinnacle device infringe Accent's patent rights." Slip op. at 15 (quoting *High Tech Med. Instrumentation v. New Image Indus., Inc.*, 49 F.3d 1551, 1556 (Fed. Cir. 1995)).

The Federal Circuit reversed, holding that the claims do not require four elongated operator bodies. The Court reasoned that "Leggett can only arrive at its added limitation requiring four elongated operator bodies by construing 'each' and 'a respective one' to require that each of the elongated operator bodies correspond to one and only one of the gripper, knotter, cutter, and cover." Slip op. at 11-12. The Court

noted that "in the preferred embodiment of the invention, two elongated operator bodies are operably coupled to both the knotter and the cover," and that "a claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct." *Id.* at 12 (quoting *On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1138 (Fed. Cir. 2004)). Because Leggett did not contest Accent's assertion that, without a limitation requiring at least four elongated operator bodies, the Pinnacle device infringes claims 1-4 of the '877 patent, the Federal Circuit directed the district court to enter SJ in favor of Accent on those claims.

The remaining asserted claims require a "mount" that permits pivoting through an arc "of at least about 90°." The district court determined that the Pinnacle's mount does not pivot 90 degrees, and thus does not infringe. Accent argued that but for Pinnacle's "SafeLatchTM" stop, which can be easily removed by the user, the Pinnacle's mount would permit its cover to pivot through the required ninety-degree arc. Affirming the district court, the Federal Circuit rejected this argument, noting that the SafeLatchTM serves a "critical safety and service function," and explaining that a "device does not infringe simply because it is possible to alter it in a way that would satisfy all the limitations of a patent claim." *Id.* at 14-15 (quoting *High Tech Med. Instrumentation v. New Image Indus., Inc.*, 49 F.3d 1551, 1555 (Fed. Cir. 1995)).

With regard to the district court's denial of Accent's Rule 56(d) motion for additional discovery, the Federal Circuit rejected Accent's argument that additional discovery would have allowed Accent to discover whether Leggett intended or anticipated that the Pinnacle device would be operated without the SafeLatchTM stop. The Court noted that district courts have "wide discretion in managing discovery matters," and that "the evidence already produced indicated that customers would have no rational reason to remove the SafeLatchTM stop." *Id.* at 17.

Accent also challenged the district court's dismissal of Accent's claim under the MUTSA, asserting that the specifications and tolerances of its 470 device are trade secrets, and that Leggett misappropriated those trade secrets by obtaining and copying a 470 device. The Federal Circuit affirmed the dismissal, noting that Accent's own complaint both acknowledged that the 470 device was sold in the regular stream of commerce and alleged that the 470 device is covered by the '877 and '992 patents. The Court explained that "[i]nformation that can be obtained from examining products sold into the public domain . . . cannot constitute a trade secret," and that "any specifications and tolerances disclosed in or ascertainable from the asserted patents became publicly available in October 2005 when the '877 patent application was published and, as such, could not constitute a trade secret." *Id.* at 18-19.

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Sufficient Controversy Exists for DJ Jurisdiction Where Patentee Had Accused DJ Plaintiff of Misappropriating Same Technology in Related Litigation

Clara N. Jimenez

Judges: Dyk (author), Plager, O'Malley [Appealed from E.D. Penn., Judge Yohn]

In Arkema Inc. v. Honeywell International, Inc., No. 12-1308 (Fed. Cir. Feb. 5, 2013), the Federal Circuit held that the district court erred in its determination that there was no Article III case or controversy between the parties regarding the infringement and validity of the asserted patents. Accordingly, the Federal Circuit reversed the district court's denial of the plaintiffs' motion to supplement its complaint to add DJ claims with respect to the asserted patents.

Honeywell International, Inc. ("Honeywell") and plaintiffs Arkema Inc. and Arkema France (collectively "Arkema") compete in the manufacture and sale of automotive refrigerants, and have invested substantial resources in the manufacture of HFO-1234yf ("1234yf"), a refrigerant developed in response to new regulations in the European Union. Honeywell holds a number of patents directed to the refrigerant, including European Patent No. 1,716,216 ("the European patent") and U.S. Patent Nos. 7,279,451 ("the '451 patent") and 7,534,366 ("the '366 patent"). Honeywell sued Arkema in Germany for infringement of the European patent. In response, Arkema filed a DJ action in the United States over the '451 and '366 patents. While in discovery, Honeywell was granted U.S. Patent Nos. 8,033,120 ("the '120 patent") and 8,065,882 ("the '882 patent"). Both patents are directed to methods of using the refrigerant in automobile air conditioning systems. Arkema moved to supplement its complaint to seek DJ of noninfringement and invalidity as to the '120 and '882 patents, fearing liability under those patents arising from the sale of the refrigerant to U.S. automobile manufacturers. The district court denied Arkema's motion to supplement, finding that while there would be no undue prejudice to Honeywell if Arkema were permitted to supplement, the new claims did not present a "case or controversy" under Article III of the U.S. Constitution. Arkema appealed.

On appeal, the Federal Circuit reviewed the district court's conclusion that Arkema's supplemental claims were not justiciable. The Court explained that the proper test of when an action for DJ presents a justiciable controversy is "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Slip op. at 8 (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)). The Court noted that "[o]n its face, [the case] is a quintessential example of a situation in which declaratory relief is warranted." *Id.* at 9. For example, the Court found that Arkema faced significant liability if it proceeded with its plans to enter into contracts and subsequently supply automobile manufacturers with the refrigerant. Honeywell made it clear that it would protect its patent rights against any such activity by Arkema, and in fact had already asserted its rights in the same technology in Europe. Thus, because Arkema was seeking a determination of a legal right

under the method patents covering its own activities, the Court concluded that there was a controversy between Arkema and Honeywell as to the rights in the 1234yf refrigerant technology.

"Even under the now-discarded reasonable apprehension of suit test, it was well established that a sufficient controversy existed for declaratory judgment jurisdiction where the patentee had accused the declaratory judgment plaintiff of misappropriating the same technology in related litigation." Slip op. at 11 (footnote omitted).

The Court next addressed each of the district court's reasons for concluding that there was no justiciable controversy. First, the district court determined that "Arkema has neither alleged nor offered evidence that an Arkema customer has committed an act of direct infringement." *Id.* (citation omitted). The Federal Circuit explained that no specific infringing acts were necessary for DJ jurisdiction. It further explained that Honeywell need not have directly accused Arkema of potential indirect infringement. Rather, according to the Court, "a sufficient controversy existed for declaratory judgment jurisdiction where the patentee had accused the declaratory judgment plaintiff of misappropriating the same technology in related litigation." *Id.* at 11. Here, the Court concluded that Honeywell's accusing Arkema of infringing its rights with respect to 1234yf in litigation over the closely related '366 patent and the European patent claiming methods of using 1234yf created a sufficiently affirmative act on the part of the patentee for DJ purposes.

Second, the district court found that Arkema did not allege an adequate "specific planned activity" because the district court found that there were methods for using 1234yf in an automobile air conditioning system that would not infringe the '120 and '882 method patents. *Id.* at 12. The Federal Circuit, however, found that the evidence demonstrated that there were no noninfringing uses for 1234yf in automobile air conditioning systems and that Arkema admitted that any design employing 1234yf in an automobile would infringe the claims of the '120 and '882 patents. The Court found no question that Arkema would arguably be liable for induced infringement and thus concluded that the controversy was "sufficiently real" for purposes of DJ jurisdiction. *Id.* at 13.

Third, the district court found that any "threshold acts of direct infringement are not sufficiently immediate to create a justiciable controversy" because "the first predicted commercial launch of any product using [1234yf] is at least one year away." *Id.* (alteration in original) (citation omitted). The Federal Circuit disagreed. Because Arkema had already entered into long-term supply contracts, the Court concluded that Arkema presently had to either commit to contracts that could expose it to liability for indirect infringement or abandon its plans to supply 1234yf to automobile manufacturers in the United States. Accordingly, the Court concluded that Arkema's need for a DJ clarifying its rights was sufficiently immediate under Article III.

Finally, the district court concluded that Arkema had not satisfied the "'reality' requirement" under *MedImmune* because it had not demonstrated that the design of its customers' products was sufficiently fixed. *Id.* at 13-14. The Federal Circuit, however, found that Arkema had clear plans to sell 1234yf for use as the refrigerant component of heat transfer compositions for automobile air conditioning systems. The Court reiterated that there was no uncertainty about whether Arkema's product was going to be used in a way that might or might not have infringed Honeywell's rights. Accordingly, the Court concluded that the controversy between Honeywell and Arkema regarding the '120 and '882 patents was "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* at 15 (quoting *MedImmune*, 549 U.S. at 127).

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No Federal Cause of Action Based on Assignor Estoppel

Benjamin A. Saidman

Judges: Lourie (author), Bryson, Wallach [Appealed from N.D. Cal., Judge Breyer]

In Semiconductor Energy Laboratory Co. v. Nagata, No. 12-1245 (Fed. Cir. Feb. 11, 2013), the Federal Circuit affirmed the district court's decision that there was no federal cause of action based on the affirmative application of assignor estoppel. The Court also held that the district court did not abuse its discretion in declining supplemental jurisdiction over the state law claims.

Semiconductor Energy Laboratory Co., Ltd. ("SEL") owns U.S. Patent No. 6,900,463 ("the '463 patent"), which names Dr. Yujiro Nagata as a coinventor. During prosecution of the '463 patent, Nagata assigned his rights in the '463 patent to SEL's founder, Dr. Shunpei Yamazaki. SEL later brought suit for infringement of a number of patents, including the '463 patent, against Samsung, Inc. ("Samsung") and others in the U.S. District Court for the Western District of Wisconsin. SEL contacted Nagata for assistance in the litigation, but Nagata had previously agreed to assist Samsung in the litigation as a fact witness. During the Wisconsin proceedings, Nagata gave testimony repudiating his signature on the documents assigning rights to SEL, leading to an inequitable conduct claim by Samsung against SEL. The Wisconsin dispute eventually settled.

SEL then brought suit against Nagata in the U.S. District Court for the Northern District of California, asserting five causes of action in its amended complaint: (1) DJ for violation of federal patent law via assignor estoppel; (2) DJ for anticipatory breach of contract; (3) slander of title; (4) quiet title; and (5) unjust enrichment. The district court dismissed SEL's complaint with prejudice for lack of subject matter jurisdiction under 28 U.S.C. § 1331 because the doctrine of assignor estoppel did not provide a cognizable federal cause of action. SEL appealed.

"[A]ssignor estoppel is a form of estoppel, and with rare exception, estoppel is a shield; it is an affirmative defense, not a claim for relief on its own." Slip op. at 7.

On appeal, the Federal Circuit affirmed the district court's conclusion that SEL neither established that federal patent law created a cause of action as pleaded nor that federal patent law was a necessary element of its claims. According to the Court, the only claim asserted by SEL purporting to arise under federal patent law—a DJ for violation of federal patent law—was premised on the doctrine of assignor estoppel. The Court explained that "assignor estoppel is a form of estoppel, and with rare exception, estoppel is a shield; it is an affirmative defense, not a claim for relief on its own." Slip op. at 7

(citing Fed. R. Civ. P. 8(c)(1)).

The Federal Circuit then turned to whether federal patent law was a necessary element of SEL's state law claims. Again affirming the district court, the Court concluded that "SEL's contrived federal issue is not a necessary element of its state law claims, which are each independent issues of state law, separately supported by alternative state law theories that do not necessarily require resolution of any disputed substantial question of federal patent law." *Id.* at 9 (citing *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005)). The Court continued, "'[T]he mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction." *Id.* (alteration in original) (quoting *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 813 (1986)).

Lastly, with respect to supplemental jurisdiction under 28 U.S.C. § 1367(a), the Federal Circuit held that because the district court correctly dismissed SEL's purported federal law claim, the district court did not abuse its discretion in declining to exercise supplemental jurisdiction over SEL's remaining state law claims. Thus, the Court affirmed the judgment of the district court.

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O2 Micro Does Not Apply When Jury Explicitly Told by Court to Use Only the Court's Claim Construction

Coalton S. Bennett

Judges: Rader, Newman, Reyna (author)

[Appealed from E.D. Tex., Magistrate Judge Everingham IV]

In Function Media, L.L.C. v. Google Inc., No. 12-1020 (Fed. Cir. Feb. 13, 2013), the Federal Circuit affirmed the district court's determination that one patent was invalid as indefinite and the jury's verdict that two other patents were invalid and not infringed. The Court also held that the district court did not abdicate its responsibility to construe the disputed claim terms or incorrectly deny a motion for new trial, finding that the verdicts of infringement and invalidity were not irreconcilable.

Function Media, L.L.C. ("FM") filed suit against Google Inc. ("Google"), claiming that Google infringed U.S. Patent Nos. 6,446,045 ("the '045 patent"); 7,240,025 ("the '025 patent"); and 7,249,059 ("the '059 patent"). The purpose of the invention is to facilitate advertising on multiple advertising outlets, such as newspapers and websites, by automatically formatting the ads to fit each publisher's requirements and sending them out for publication. After claim construction, the district court held that the '045 patent was indefinite and therefore invalid because the specification lacked sufficient structure for the claim's mean-plus-function term, "means for transmitting." The jury found the claims of the '025 and '059 patents to be invalid and not infringed. In post-trial motions, FM argued that the verdict was against the great weight of evidence and irreconcilable. The district court granted JMOL for certain claims of the '025 patent, finding that Google did not submit sufficient evidence for the jury to find that those claims were invalid. Therefore, these claims remained valid and not infringed. FM appealed.

"While it may seem harsh, requiring objections to be made before the jury is dismissed is the only way to efficiently cure potential inconsistencies when there is not a detailed special verdict to review." Slip op. at 32.

Turning first to the means-plus-function claim, the Federal Circuit held that, "[a]t most, the '045 Patent specification discloses that the structure behind the function of transmitting is a computer program that transmits," but beyond the program's function, no algorithm describing the transmission function is disclosed. Slip op. at 10-11. Citing *Aristocrat Technologies Australia Pty Ltd. v. International Game Technology*, 521 F.3d 1328, 1333 (Fed. Cir. 2008), the Court disagreed with FM's argument that a person skilled in the art could provide an operative software program for the specified function, holding that the patentee is not absolved of providing an explanation about the structure of a function just because someone of ordinary skill in the art can devise a means with which to perform the claimed function.

In addition to arguing that the district court's claim constructions were incorrect, FM argued that the court improperly sent the construction to the jury, running afoul of O2 Micro International v. Beyond Innovation Technology Co., 521 F.3d 1351, 1362 (Fed. Cir. 2008). In O2 Micro, the Federal Circuit held that "[w]hen the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it." Slip op. at 21 (alteration in original) (quoting O2 Micro, 521 F.3d at 1362). Here, FM attempted to establish such an unresolved dispute by relying on the district court's denial of SJ of noninfringement, a disagreement by the parties over expert testimony misstating the court's claim construction, and by certain statements made by Google during closing argument. But, the Federal Circuit did find that O2 Micro did not apply. In O2 Micro, the district court did not settle a claim construction dispute, so the parties presented their arguments to the jury, and the Federal Circuit found this was error and remanded for the district court to construe the claims in the first instance. But, the Court concluded that this case was more like Verizon Services Corp. v. Cox Fibernet Virginia, Inc., 602 F.3d 1325 (Fed. Cir. 2010), where the issue was whether there were improper attorney arguments, not whether questions of claim scope were submitted to the jury. The Court decided that in this case, as in Verizon, "the jury was explicitly told by the court to use only the court's claim construction." Slip op. at 24.

Finally, the Federal Circuit considered FM's argument that the verdicts of noninfringement and invalidity were irreconcilable because Google's technology worked the same way as the prior art, and, thus, FM contended that the jury had to rely on differing claim constructions for infringement and invalidity. Because FM failed to object to the verdict's irreconcilability when the jury returned its verdict, applying Fifth Circuit law, the Federal Circuit held that FM could only avoid waiver if the verdict form was considered special. But the Court found that "the portion of the verdict in which the jury applied facts to law on the question of obviousness was clearly a general verdict because it is a legal question resting on underlying factual questions." Id. at 29. Further, the Court reasoned that, "[a]lthough the jury was technically finding only 'facts,' we hold that the verdict is a general verdict because like the questions in [Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506 (Fed. Cir. 1984)], the questions on anticipation and validity require legal instruction, the application of legal principles, and are more than 'simply written finding[s] upon each issue of fact." Slip op. at 31 (third alteration in original) (citing Bettecher Indus., Inc. v. Bunzl USA, Inc., 661 F.3d 629, 641-42 (Fed. Cir. 2011)). Thus, in dismissing FM's claim, the Federal Circuit concluded that, "[w]hile it may seem harsh, requiring objections to be made before the jury is dismissed is the only way to efficiently cure potential inconsistencies when there is not a detailed special verdict to review " Slip op. at 31-32.

The Federal Circuit also affirmed a number of the court's claim constructions, relying on the plain language of the claims and found that sufficient evidence supported the verdict of noninfringement; thus, the district court did not abuse its discretion in denying FM's motion for a new trial. In sum, the Federal Circuit affirmed the judgment that FM's patents are invalid and not infringed.

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To Prove Lack of Enablement, the Challenger Must Present More Than Mere Unsubstantiated Expert Testimony That Undue Experimentation Is Required to Practice the Invention

Angela Y. Dai

Judges: Reyna, Bryson, Wallach (author)
[Appealed from D. Del., Judge Robinson]

In Cephalon, Inc. v. Watson Pharmaceuticals, Inc., No. 11-1325 (Fed. Cir. Feb. 14, 2013), the Federal Circuit reversed the district court's finding that the asserted patents were invalid for lack of enablement, and affirmed the district court's finding of noninfringement.

Cephalon, Inc. and CIMA Labs, Inc. (collectively "Cephalon") are holders of the NDA for fentanyl buccal tablets, sold under the brand name FENTORA® for the treatment of breakthrough cancer pain.

U.S. Patent Nos. 6,200,604 ("the '604 patent") and 6,974,590 ("the '590 patent") (collectively "the Khankari patents") are listed in the FDA's Orange Book for FENTORA® and cover methods of administering a fentanyl tablet containing an effervescent agent and a pH adjusting substance via the mucous membrane lining or mucosa in the oral cavity.

Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc. (collectively "Watson") filed an ANDA seeking approval to market a generic version of FENTORA®. In response, Cephalon sued Watson for patent infringement, first asserting the Khankari patents and later asserting an additional patent in a subsequent suit. The district court consolidated the two actions and after a bench trial concluded that Cephalon did not prove, by a preponderance of the evidence, that Watson's ANDA products infringed either of the Khankari patents. The district court also found that Watson proved, by clear and convincing evidence, that the Khankari patents were invalid for lack of enablement. Further, the district court found that Watson failed to show that the asserted patents were invalid as anticipated or obvious in view of prior art. Cephalon appealed the ruling with respect to the Khankari patents.

On appeal, the Federal Circuit first addressed whether the district court erred in ruling that Watson had carried its burden of proving, by clear and convincing evidence, that the Khankari patents were invalid for lack of enablement. The dispute arose from the district court's construction of the term "effervescent agent" in claim 1 of the Khankari patents to require "at least one compound that evolves gas by means of an effervescent reaction," and its conclusion that "effervescent agent" referred to a single compound. Slip op. at 10 (quoting Cephalon, Inc. v. Watson Pharms., Inc., 769 F. Supp. 2d 729, 744 (D. Del. 2011)). The effervescent reaction, which may play a role in increasing the rate and extent of absorption of an active drug, is most often the result of a soluble acid source, like citric acid, reacting with a source of carbon dioxide that is mostly basic, like an alkaline carbonate or bicarbonate. The district court's "single compound effervescent agent" construction required the soluble acid source to be in a separate tablet or dosage form from the effervescent agent (carbonate source) and required these separate dosage forms

to be coadministered to achieve the claimed effervescent reaction.

"Because we must presume a patent enabled, the challenger bears the burden, throughout the litigation, of proving lack of enablement by clear and convincing evidence." Slip op. at 12.

The district court found that formulating and coadministering two separate dosage forms to achieve an effervescent reaction necessitated undue experimentation, and determined that Watson established a prima facie case of lack of enablement, which Cephalon failed to rebut. The Federal Circuit, however, noted that the burden of proof was Watson's alone. "Because we must presume a patent enabled, the challenger bears the burden, throughout the litigation, of proving lack of enablement by clear and convincing evidence." *Id.* at 12 (citing *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1469-70 (Fed. Cir. 1993)).

In determining that Watson did not meet its burden of proof, the Court noted that Watson relied heavily on its expert's unsubstantiated testimony that coadministration would be difficult and complicated. The Court found such ipse dixit statements insufficient to constitute clear and convincing evidence. The Court noted that the district court's reliance on Cephalon's expert testimony that routine experimentation would be required to create an effervescent reaction by coadministering two dosage forms to support Watson's position of undue experimentation was misplaced. The Court explained that "[t]he question of undue experimentation is a matter of degree, and what is required is that the amount of experimentation not be 'unduly extensive." Id. at 13-14 (citing Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1253 (Fed. Cir. 2004)). The Court noted that the focus "is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance." Id. at 14 (quoting PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996)). The Court further noted, however, that "[p]ermissible experimentation is . . . not without bounds." Id. For example, the Court has held that experimentation is unreasonable where (1) eighteen months to two years' work is required to practice the patented invention; (2) the specification lacks guidance by teaching away from the subject matter that is eventually claimed; and (3) there is evidence of the patentee's own failures to make and use the later claimed invention at the time of the application.

Here, the Court found that Watson presented no evidence showing why the formulations for an effervescent "couple"—where the soluble acid source and the effervescent agent are in the same dosage form—described in the Khankari patents did not provide sufficient guidance for a skilled artisan to calculate formulations for single compound effervescent agents without undue experimentation. Nor did Watson show that the resulting experimentation in this case would be excessive. Finding that record evidence did not sufficiently show that the experimentation necessary for coadministration would be unduly extensive, the Court concluded that the district court erred as a matter of law in holding that Watson proved its case on enablement by clear and convincing evidence, and reversed the district court's nonenablement determination.

Next, the Court addressed the district court's ruling that Watson did not infringe the asserted claims. The disputed claim limitation addressed on appeal was "at least one [saliva activated] effervescent agent in an amount sufficient to increase absorption . . . across [the] oral mucosa." *Id.* at 18 (alterations in original) (quoting *Cephalon*, 769 F. Supp. 2d at 748). The district court's construction of this limitation required the effervescent agent to be "saliva activated," and the parties' dispute centered on whether potassium bicarbonate and mannitol in the ANDA products reacted to generate an effervescent reaction. The district court found that while Cephalon presented evidence of acidity of mannitol in water, it did not provide any evidence of acidity of mannitol in artificial or human saliva. Agreeing with the district court, the Federal Circuit determined that Cephalon failed to prove that the limitation was practiced by the ANDA products, either literally or under the DOE.

Accordingly, the Federal Circuit reversed the district court's judgment of invalidity and affirmed the district court's judgment of noninfringement.

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A Claim Element Is Vitiated If No Equivalent Exists in an Accused Infringing Device Based on Either the "Function-Way-Result" or "Insubstantial Differences" Tests

Ray Huang

Judges: Dyk (concurring-in-part and dissenting-in-part), Moore (author), Reyna [Appealed from N.D. Cal., Judge Wilken]

In *Brilliant Instruments, Inc. v. GuideTech, LLC*, No. 12-1018 (Fed. Cir. Feb. 20, 2013), the Federal Circuit reversed the district court's grant of SJ for noninfringement and remanded the case to the district court.

Brilliant Instruments, Inc. ("Brilliant") filed a DJ action on GuideTech, LLC's ("GuideTech") three patents: U.S. Patent Nos. 6,226,231 ("the '231 patent"); 6,091,671 ("the '671 patent"); and 6,181,649 ("the '649 patent"). The three patents relate to circuits that measure the timing errors of digital signals. Claim 1 of the '231 patent requires "a plurality of measurement circuits defined within said signal channel." Claim 1 of the '671 patent and claim 1 of the '649 patent require a capacitor that is "operatively disposed in parallel with respect to said first current circuit." The district court construed the above claim terms and entered SJ of noninfringement in favor of Brilliant for all three patents.

On appeal, with regard to the '231 patent, the Federal Circuit held that the district court erred in granting SJ. The Court noted that the district court construed the claim term "defined within said signal channel" as "contained within a signal channel," and that neither party challenged this construction. Slip op. at 5 (citation omitted). Based on the relevant circuit schematics and the expert testimony in GuideTech's favor, the Court concluded that a genuine issue of material fact existed as to whether Brilliant's accused products, "when operating in One-Channel-Two-Edge mode, have two measurement circuits contained within a signal channel." *Id.* at 6.

"[V]itiation applies when one of skill in the art would understand that the literal and substitute limitations are not interchangeable, not insubstantially different, and when they do not perform substantially the same function in substantially the same way, to accomplish substantially the same result." Slip op. at 10.

With regard to the '671 and '649 patents, the Federal Circuit held that the district court properly granted SJ that Brilliant's accused products did not literally infringe. The Court stated that GuideTech could not establish literal infringement because, in Brilliant's accused products, it was undisputed that the capacitor was part of the first current circuit, while claim 1 of the '671 patent and claim 1 of the '649 patent required the capacitor to be "operatively disposed in parallel" with respect to the first current circuit.

The Federal Circuit, however, held that the district court erred when it granted SJ of noninfringement under the DOE. The Court disagreed with Brilliant's argument that GuideTech's DOE infringement theory vitiated the requirement that the claimed "first current circuit" and the "capacitor" be separate claim elements. The Court reiterated that "'[v]itiation' is not an exception to the doctrine of equivalents." *Id.* at 9 (quoting *Deere & Co. v. Bush Hog, LLC*, Nos. 11-1629, -1630, -1631, 2012 WL 6013405, at *5 (Fed. Cir. Dec. 4, 2012)). Moreover, "the vitiation test cannot be satisfied by simply noting that an element is missing from the claimed structure or process because the doctrine of equivalents, by definition, recognizes that an element is missing that must be supplied by the equivalent substitute." *Id.* at 10 (quoting *Deere*, 2012 WL 6013405, at *5).

Instead, the Federal Circuit held that "vitiation applies when one of skill in the art would understand that the literal and substitute limitations are not interchangeable, not insubstantially different, and when they do not perform substantially the same function in substantially the same way, to accomplish substantially the same result." *Id.* According to the Court, a claim element would be vitiated if no equivalent exists in the accused infringing device based on either the "function-way-result" or the "insubstantial differences" tests. *Id.* To succeed on a DOE theory, "the patentee must demonstrate equivalence under one of these two tests." *Id.*

In this case, the Federal Circuit reasoned that the proper DOE inquiry should be: "did GuideTech create a genuine issue of material fact regarding whether Brilliant's capacitor, located within the first current circuit, performs substantially the same function in substantially the same way to achieve substantially the same result as the claimed capacitor . . . ?" Id. at 11. The Court answered this question in favor of GuideTech based on GuideTech's expert applying the function-way-result test to the accused product, concluding that GuideTech created a genuine issue of material fact that precludes SJ of noninfringement under the DOE.

Accordingly, the Federal Circuit reversed and remanded the case to the district court.

Judge Dyk concurred-in-part and dissented-in-part. Judge Dyk agreed with the majority with respect to the '231 patent, and that there was no literal infringement of the '671 and '649 patents. Judge Dyk disagreed, however, that a genuine issue of material fact remained as to infringement of the '671 and '649 patents under the DOE. According to Judge Dyk, the DOE "must be applied to *individual limitations* of the claim, not to the invention as a whole." Dyk Dissent at 3 (quoting Mirror Worlds, LLC v. Apple Inc., 692 F.3d 1351, 1357 (Fed. Cir. 2012)). According to Judge Dyk, GuideTech's expert applied the equivalent to the invention as a whole rather than to the particular claim limitation at issue. Specifically, Judge Dyk stated that the expert report failed to explain why the change in location of the disputed capacitor was an insubstantial difference and how the function-way-result test was satisfied as to the claim limitation. Thus, Judge Dyk concluded that the district court's judgment of noninfringement as to the '671 and '649 patents under the DOE should have been affirmed.

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Spotlight Info

In Arkema Inc. v. Honeywell International, Inc., No. 12-1308 (Fed. Cir. Feb. 5, 2013), the Federal Circuit held that the district court erred in its determination that there was no Article III case or controversy between Honeywell International, Inc. ("Honeywell") and Arkema Inc. ("Arkema") regarding the infringement and validity of certain patents relating to HFO-1234yf ("1234yf"), an automotive refrigerant. Arkema had filed a DJ action over Honeywell's patents, and when Honeywell was granted two additional patents directed to using the refrigerant in automobile air conditioning systems, Arkema moved to supplement its complaint to seek DJ of noninfringement as to the two additional patents, fearing liability under those patents arising from the sale of the refrigerant to U.S. automobile manufacturers. In holding Arkema's supplemental claims justiciable, the Court held that no specific infringing acts were necessary for DJ jurisdiction, and that a sufficient controversy existed for DJ jurisdiction "where the patentee had accused the declaratory judgment plaintiff of misappropriating the same technology in related litigation." Slip op. at 11. The Court concluded that Honeywell's accusing Arkema of infringing its rights with respect to 1234yf in litigation created a sufficiently affirmative act on the part of the patentee for DJ purposes. See this month's edition of Last Month at the Federal Circuit for a full summary of this decision.

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Looking Ahead

In a 2-1 decision in *In re Hubbell*, No. 11-1547 (Fed. Cir. Mar. 7, 2013), the Federal Circuit affirmed a determination by the Board upholding the rejection of the claims of U.S. Application No. 10/650,509 ("the '509 application") for obviousness-type double patenting over U.S. Patent No. 7,601,685 ("the '685 patent"). The '509 application and the '685 patent are directed to the field of tissue repair and regeneration, and more specifically to matrices containing bidomain peptides or proteins.

During prosecution, the examiner determined that the conflicting claims in the '685 patent were directed to species of the claimed invention of the '509 application and therefore anticipated the claimed invention of the '509 application. The Board affirmed the obviousness-type double patenting rejection over the '685 patent.

On appeal before the Federal Circuit, Appellants argued that obviousness-type double patenting should not apply where an application and a conflicting patent share common inventors but do not have identical inventive entities, were never commonly owned, and are not subject to a joint research agreement. Alternatively, Appellants argued that they should be allowed to file a terminal disclaimer as an equitable measure, or that the Court should employ a two-way obviousness analysis for the rejected claims.

The majority rejected both arguments and affirmed the Board's determination. Judge Newman dissented. Watch for the complete case summary in the next edition of *Last Month at the Federal Circuit*.

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