

NOTE: Pursuant to Fed. Cir. R. 47.6, this disposition is not citable as precedent. It is a public record.

United States Court of Appeals for the Federal Circuit

03-1204

KEMIN FOODS, L.C.
and THE CATHOLIC UNIVERSITY OF AMERICA,

Plaintiffs-Appellees,

v.

PIGMENTOS VEGETALES DEL CENTRO S.A. DE C.V.,

Defendant-Appellant.

DECIDED: March 17, 2004

Before LOURIE, DYK, and PROST, Circuit Judges.

LOURIE, Circuit Judge.

Pigmentos Vegetales del Centro S.A. de C.V. (“PIVEG”) appeals from the January 7, 2003 Supplemental Order of the United States District Court for the Southern District of Iowa, preliminarily restraining and enjoining it from “continuing to infringe United States Patent No. 5,382,714, including by making, importing, or selling within the United States lutein crystals from plant extracts with a purity level of 90 percent or greater and/or suitable for human consumption.” Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V., 240 F. Supp. 2d 982 (S.D. Iowa 2003) (“Supplemental Order”). Because the district court erred in its construction of the claims of the ’714 patent and in its assessment of the validity and enforceability of that patent, and thus seriously misjudged the Plaintiffs-Appellees’ likelihood of success on the merits of their case, we hold that the court abused its discretion by

restraining and enjoining PIVEG and reverse the grant of a preliminary injunction.

BACKGROUND

Kemin Foods, L.C. is the licensee of the '714 patent, owned by the Catholic University of America ("CUA"), and of United States Patent 5,648,564, owned by Kemin Industries, Inc. The '714 and '564 patents are directed to a composition consisting essentially of substantially purified lutein crystals and a lutein extraction method, respectively.

PIVEG is a Mexican company that traditionally made lutein-containing poultry feed supplements used to enhance the yellow coloration of egg yolks. After scientists apparently unaffiliated with any of the parties in this case discovered that lutein also has human nutritional benefits, PIVEG began marketing purified lutein crystals suitable for human consumption in the United States. Kemin Foods, L.C. and CUA (collectively, "Kemin") then filed suit against PIVEG in the Southern District of Iowa on July 9, 2002, alleging infringement of the '714 and '564 patents. Kemin also moved for a preliminary injunction with respect to both patents. In opposition to Kemin's motion, PIVEG denied infringing either of the asserted patents and also contended that the '714 patent is invalid under 35 U.S.C. § 102 and unenforceable for inequitable conduct due to Kemin's failure to cite a prior art article, Juliusz K. Tyczkowski & Pat B. Hamilton, Research Note: Preparation of Purified Lutein and Its Diesters from Extracts of Marigold (*Tagetes erecta*), 70 Poultry Sci. 651 (1991) ("the Poultry Science article").

Following a hearing on Kemin's motion for a preliminary injunction, the district court concluded that Kemin was likely to succeed on the merits of its claim with respect to the '714 patent, but not the '564 patent. Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V., 240 F. Supp. 2d 963, 981 (S.D. Iowa 2003) ("Preliminary Order"). In reaching that conclusion, the court rejected PIVEG's argument that the claims of the '714 patent were anticipated by the Poultry Science article. Id. at 971. Although the court found a "strong indication of materiality" of that article, the court credited the testimony of Kemin Industries Worldwide's president that Kemin had attempted to reproduce the results described in the article and found the method to be inoperative. Id. On that basis, the court also concluded that Kemin lacked the requisite intent for a finding of inequitable conduct. Id. at 974. The

court then compared PIVEG's marketing materials to the asserted claims of the '714 and '564 patents and concluded that Kemin could likely show infringement of the former patent, *id.*, but that the evidence adduced by Kemin was insufficient to show a substantial likelihood that PIVEG was using the method claimed in the latter patent, *id.* at 978.

The court also found that Kemin would likely suffer irreparable harm if PIVEG's product were allowed to remain on the market, especially in view of an admission by PIVEG that it had no U.S. assets, *id.* at 979-80; that the balance of hardships in this case tilted slightly in Kemin's favor because lutein for use as a human dietary supplement is its only product, *id.* at 980; and that a preliminary injunction would benefit the public's interest in protecting patent rights, *id.* at 981. The court accordingly granted Kemin's motion for a preliminary injunction in part, enjoining infringement of the '714 patent, "including by making, using, importing, or selling within the United States purified lutein crystals from plant extracts," but not the '564 patent. *Id.* at 981-82.

Several days later, PIVEG requested clarification of the terms of the preliminary injunction from the district court, arguing that the phrase "purified lutein crystals from plant extracts" was unclear. Over Kemin's objection, the court narrowed the scope of the injunction by adding "with a purity level of 90 percent or greater and/or suitable for human consumption" after the phrase alleged to be unclear. Supplemental Order, 240 F. Supp. 2d at 983.

PIVEG timely appealed from the grant of the preliminary injunction, and Kemin cross-appealed from the denial of a preliminary injunction with respect to the '564 patent. We have jurisdiction pursuant to 28 U.S.C. § 1338(a).

The preliminary injunction was stayed by this court in April 2003, pending the outcome of this appeal. Also, upon Kemin's motion, we have dismissed its cross-appeal. Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V., 74 Fed. Appx. 55 (Fed. Cir. 2003).

DISCUSSION

On appeal, PIVEG asserts that the preliminary injunction granted by the district court failed to comply with Federal Rules of Civil Procedure 52(a) and 65(d). In particular, PIVEG argues, the court

did not specifically construe any of the claims of the '714 patent and also failed to engage in a limitation-by-limitation infringement analysis. According to PIVEG, its human lutein product is only 87% +/- 2% pure, whereas the '714 specification and examples reveal that “substantially pure lutein” means “at least 97.62% pure.”

To the extent that the district court did construe the claims of the '714 patent, PIVEG contends, it read into them improper numerical (*i.e.*, “greater than 90% purity”) and end-use (*i.e.*, “suitable for human consumption”) limitations, and then improperly enjoined PIVEG from activities that meet those claim limitations in the disjunctive (*i.e.*, “and/or”) rather than only in the conjunctive. According to PIVEG, certain of its poultry-grade compositions are more than ninety percent pure and thus fall within the scope of the injunction despite the fact that they are not suitable for human consumption.

PIVEG also contends that the district court erred in finding that the '714 patent was not anticipated by the Poultry Science article. PIVEG argues that the district court found a “strong indication” that the Poultry Science article was a material reference, but committed reversible error by failing to recognize that a holding of invalidity on the ground of anticipation does not require intent on the part of the patentee to withhold the anticipating reference. According to PIVEG, the court also erred by failing to make any findings as to whether the composition disclosed in the Poultry Science article was suitable for human consumption. PIVEG also asserts that it was able to reproduce the results of the Poultry Science article without undue experimentation, despite Kemin’s argument that the article did not contain an enabling disclosure.

The court further erred, according to PIVEG, in failing to find inequitable conduct. Whether prior art is enabled is irrelevant to the duty of disclosure, PIVEG argues, and the Poultry Science article should have been disclosed. Moreover, a mere denial of bad faith is insufficient to overcome evidence to the contrary. In particular, PIVEG alleges, Kemin itself supplied samples to the authors of the Poultry Science article, thereby indicating the relevance of the article to Kemin’s patent, and Kemin’s argument that that article was not material was merely an after-the-fact rationalization. Indeed, PIVEG points out, Kemin expressed its recognition that the article was material by citing it during prosecution of the

application that led to the '564 patent.

Kemin agrees with PIVEG that numerical and end-use limitations should not have been read into the claim, but contends that not doing so would not change the outcome of this case. According to Kemin, the original injunction paralleled the scope of claim 1 of the '714 patent; numerical and end-use limitations were added to the injunction order at PIVEG's request, and it should therefore be estopped from denying them now. In any event, according to Kemin, its tests show that PIVEG's lutein is 92.63% pure and is accordingly within the scope of the claim even if construed to require both 90% or greater purity and suitability for human consumption.

Responding to PIVEG's invalidity and unenforceability arguments, Kemin argues that PIVEG's expert admitted that the process described in the Poultry Science article was inoperative as written and required modification. According to Kemin, PIVEG has not provided any evidence of an intent to deceive by Kemin, and the district court correctly found that the Poultry Science article was merely cumulative of other prior art. Kemin asserts that PIVEG has wrongfully equated prior knowledge of the existence of a reference with knowledge of its materiality.

We conclude that the district court partially misconstrued the claims and that Kemin did not show a likelihood of success in regard to infringement. Even if we assumed that Kemin had satisfied that inquiry, we find that PIVEG has raised a substantial question as to the validity and enforceability of the '714 patent. The district court therefore abused its discretion by granting the preliminary injunction.

Injunctive relief in patent cases is authorized by 35 U.S.C. § 283. In ruling on a motion for a preliminary injunction, a court must consider the following four factors: (1) the moving party's reasonable likelihood of success on the merits; (2) whether the moving party will suffer irreparable harm if the injunction is not granted; (3) whether the balance of hardships tips in favor of the moving party; and (4) whether the public interest would be served by the grant of an injunction. Anton/Bauer, Inc. v. PAG, Ltd., 329 F.3d 1343, 1348 (Fed. Cir. 2003). Although not all of these factors, taken individually, are necessarily dispositive, the moving party must establish at the very least both of the first two factors. Id. Moreover, in order to establish a likelihood of success on the merits, the moving party must show

that “it will likely prove infringement” at trial and that “any challenges to the validity and enforceability of its patent ‘lack substantial merit.’” Id. (quoting Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359, 1363 (Fed. Cir. 2001)).

The grant or denial of a preliminary injunction is within the sound discretion of the district court. Novo Nordisk of N. Am., Inc. v. Genentech, Inc., 77 F.3d 1364, 1367 (Fed. Cir. 1996). Accordingly, we review the decision of the district court to grant a preliminary injunction for an abuse of discretion, reversing “only upon a showing that the court abused its discretion, committed an error of law, or seriously misjudged the evidence.” Globetrotter Software, Inc. v. Elan Computer Group, Inc., 236 F.3d 1363, 1367 (Fed. Cir. 2001). “[W]e review factual findings for clear error, conclusions of law de novo, and the exercise of a district court’s discretion for a clear error of judgment in weighing relevant factors.” Nat’l Steel Car, Ltd. v. Can. Pac. Ry., Ltd., 357 F.3d 1319, 1325 (Fed. Cir. 2004).

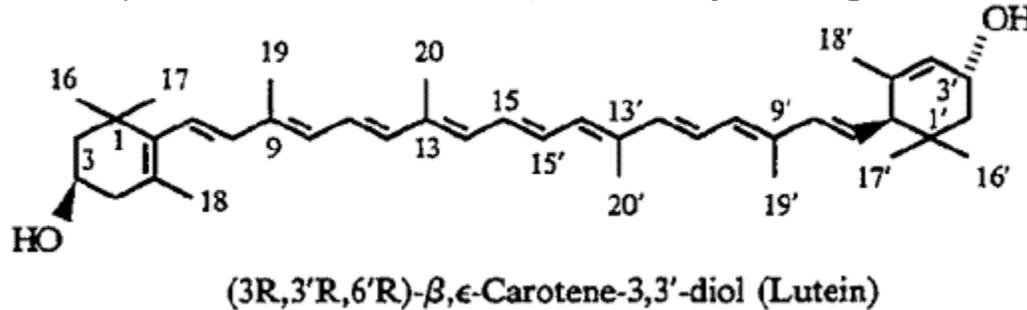
The district court made factual findings with respect to all four of the above factors and concluded that all of those factors weighed in favor of granting a preliminary injunction. We see no clear error in the court’s analysis with respect to the second, third, and fourth factors. On the present record, however, we cannot agree with the court that Kemin has shown that it is likely to prove infringement, overcome any challenges to the validity and enforceability of the ’714 patent at trial, and therefore have a reasonable likelihood of success on the merits of its case.

A. Infringement

A determination of infringement requires a two-step analysis: “First, the court determines the scope and meaning of the patent claims asserted. [Second], the properly construed claims are compared to the allegedly infringing [composition].” Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc) (citations omitted). Claim construction is a question of law, and the district court’s claim construction is accordingly reviewed *de novo*. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff’d, 517 U.S. 370 (1996). Determination of infringement is a question of fact. Bai v. L&L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998).

In reviewing the district court's construction of the claims, we begin with the language of the asserted claims. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Claims 1, 2, and 4 of the '714 patent, the only claims at issue in this appeal, read as follows:

1. The carotenoid composition consisting essentially of substantially pure lutein crystals derived from plant extracts that contain lutein, said lutein crystals being of the formula:



wherein the lutein is substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extract.

2. The lutein carotenoid composition of claim 1 wherein the plant extract is derived from naturally occurring plants selected from the group consisting of fruits, vegetables, and marigolds.
4. The lutein carotenoid composition of claim 1 wherein the lutein is derived from marigold flower extract.

'714 patent, col. 8, l. 65 - col. 9, l. 22.

The district court did not formally construe the claims. Implicit in the court's Supplemental Order, however, is the implication that the claims cover all "lutein crystals from plant extracts with a purity level of 90% or greater and/or suitable for human consumption," because that is what it enjoined PIVEG from making, using, importing, or selling. Supplemental Order, 240 F. Supp. 2d at 983. Also, in its Preliminary Order, the court explained:

The specification . . . delineates the importance of the '714 lutein crystals being suitable for human consumption. The '714 patent uses the transition phrase "consisting essentially of", which is used to exclude elements that are not specifically listed in the claim which would materially alter the novel and basic properties of

240 F. Supp. 2d at 970-71 (citation omitted).

For the reasons stated below, we essentially agree with the district court's interpretation that "substantially pure" means that lutein crystals of the claimed compositions must be at least about 90% pure, but disagree with its inclusion of the "human consumption" limitation.

The '714 patent's claims do not define the level of purity required for a composition to be deemed "substantially pure" or "substantially free from other carotenoids and chemical impurities," and thus we turn to the specification for guidance. See Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., 347 F.3d 1314, 1323 (Fed. Cir. 2003) ("Since the term 'substantially' is capable of multiple interpretations, we turn to the intrinsic evidence to determine which interpretation should be adopted."), cert. denied, 72 U.S.L.W. 3452 (U.S. Feb. 23, 2004) (No. 03-958). Like its claims, however, the '714 patent's specification does not explicitly define the term "substantially." Nonetheless, the specification does provide some guidance, stating, for example, that "[t]he purity of the resulting lutein is usually greater than 90%, most often greater than 97%." Id. at col. 5, ll. 17-18. Thus, we conclude that "substantially pure" is properly construed to mean "greater than about 90% pure."

The claims of the '714 patent also require that lutein be "substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extracts." '714 patent, claim 1. The identity of the "other carotenoids and chemical impurities" from which the compositions must be "substantially free" is not stated in the claims, but representative examples are provided in the patent's specification:

Lutein is one of the major constituents of green vegetables and fruits such as broccoli, green beans, green peas, lima beans, Brussels sprouts, cabbage, kale, spinach, lettuce, kiwi, and honeydew. The lutein in these green vegetables and fruits exists naturally in the free non-esterified form and co-exists with other carotenoids.

. . . Many expensive and time-consuming purification steps are required to remove and purify lutein from the large quantities of chlorophylls, β -carotene, and carotenoids epoxides [sic] that are also present in green vegetables.

. . . Lutein in . . . yellow/orange fruits and vegetables exists in the esterified form with fatty acids such as myristic, lauric, and palmitic acids. . . . [T]hese yellow/orange fruits and vegetables also contain high concentrations of a number of other carotenoids which make the isolation and purification of lutein costly and time-consuming.

Marigold flower petals are an excellent source of lutein because they contain high levels of lutein and no significant levels of other carotenoids. Extracts of marigold flowers are commercially available but consist of lutein that is esterified with fatty acids such as lauric, myristic, and palmitic acids.

Id. at col. 2, ll. 11-43. Accordingly, we read the claim language to be limited to compositions containing lutein crystals that are substantially free from, for example, chlorophylls, β -carotene, carotenoid epoxides, and fatty acid esters of lutein. There is no indication that any of those impurities would render the compositions unsuitable for human consumption—after all, they apparently do not render vegetables and fruits unsuitable for human consumption. Nonetheless, the presence of such impurities would take a composition outside the scope of the properly construed claims.

Although “substantially free” is also not defined, the ’714 patent’s specification states that, “[g]enerally, the concentration of other carotenoids in the starting material should be 10% or less,” id. at col. 3, ll. 57-59 (emphasis added). If the starting material (i.e., marigold petal extract prior to purification) generally contains 10% or less of other carotenoids, it follows that lutein that “is substantially free from other carotenoids . . . found in the natural form of lutein in the plant extract” must contain much less than 10% of the other carotenoids. Indeed, Example 2, the only example in the ’714 patent to specify the concentration of “other carotenoids” present in an illustrative example of a product of the invention, recites 0.23% 2’,3’-anhydrolutein, 1.51% zeaxanthin, 0.34% α -cryptoxanthin, and 0.10% β -cryptoxanthin, for a total of 2.18% “other carotenoids.” Id. at col. 7, ll. 37-41. Finally, the specification states that “the purified lutein is required not to contain even traces of any toxic chemicals.” Id. at col. 4, ll. 16-17. Accordingly, consistent with the district court’s opinion, we conclude that the claimed compositions must contain lutein crystals that are greater than about 90% pure, significantly less than 10% of other carotenoids, and no traces of toxic chemicals.

Nonetheless, it was error for the court to have read the limitation “suitable for human consumption” into the claims, either as an alternative to the 90% minimum or in conjunction with it. It may well be that all compositions that fall within the scope of claim 1 of the ’714 patent would in fact be suitable for human consumption. However, that is not what the claim requires. Although provision of lutein suitable for human consumption is certainly one of the stated objectives in the ’714 patent, see id. at col. 3, ll. 17-19, the specification also indicates that other end uses for the claimed formulations may exist, id. at col. 3, ll. 36-39.^[1]

Having construed the claims, the next step is, as explained above, to compare the properly construed claims to the allegedly infringing compositions. The district court did not make any findings as to the identity or quantity of the impurities in those compositions. Kemin asserts that PIVEG's product contains 92.63% pure lutein, in which case it would meet the "substantially pure" limitation. On the other hand, PIVEG alleges that its accused products contain only 87% +/- 2% pure lutein, which will not fall within the scope of the properly construed claims. Accordingly, we conclude that a substantial question exists concerning infringement and that Kemin has not shown that it will likely prove infringement at trial. It therefore has not demonstrated a sufficient likelihood of success on the merits of its case to support a preliminary injunction.

B. Validity and Enforceability

An issued patent is presumed to be valid, 35 U.S.C. § 282 (2000), and the burden of proving invalidity by clear and convincing evidence is on the party seeking to invalidate the patent, U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1563 (Fed. Cir. 1997). Nonetheless, we find that PIVEG has raised substantial questions as to the validity and enforceability of the '714 patent. The record is not sufficiently developed for us to decide those issues conclusively in PIVEG's favor. However, the district court's analysis with respect to those questions does not convince us that PIVEG cannot meet its burden. First, other than a conclusory statement in the Preliminary Order that PIVEG "has not created a 'substantial question' of invalidity of the '714 patent," Preliminary Order at 975, the only "discussion" of invalidity of the '714 patent is the following statement in the "Conclusion" section of the order:

The Court concludes that with respect to the '714 patent, [PIVEG] has not generated a substantial question of invalidity. Although there is a strong indication of materiality of the Poultry Science reference, [PIVEG] has not established a sufficient basis for concluding there was the requisite intentional conduct on behalf of Kemin in not disclosing the article. Thus, Kemin has demonstrated a likelihood of success on the issue of enforceability of the '714 patent.

Id. at 981. We are therefore unable to discern the basis for the court's conclusion that PIVEG did not create a substantial question of invalidity, and the above quotation in fact suggests that the district court did not distinguish between invalidity, which does not require intent, and unenforceability, which does.

[2]

Second, with regard to unenforceability, the district court found that there was “a strong indication of materiality of the Poultry Science article,” but that PIVEG “utterly failed to provide a basis for concluding any requisite intentional conduct on Kemin’s part in not disclosing the reference.” It is again difficult to discern the basis upon which the court arrived at that conclusion, although it appears to have been premised, at least in part, on the court’s finding that “[PIVEG’s] argument of materiality, as well as their argument regarding the intent of Kemin in not submitting the Poultry Science reference, presupposes the reference anticipates, claim for claim, claims 1, 2, and 4 of the ’714 patent.” Contrary to the court’s suggestion, however, there is no requirement that a reference anticipate an invention for it to be material to the patentability of the invention, as 35 U.S.C. § 102 is not the only provision bearing on patentability. A patent may be invalid over a prior art reference even if not identically disclosed or described, for example, “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103 (a) (2000). In other words, even if the reference rendered the claimed invention obvious only if combined with other prior art, it could still be highly material.

The district court apparently also relied on Kemin’s arguments that the Poultry Science article was merely cumulative with respect to other references cited in the background of the invention and that the article was not enabling. However, the record does not reflect that the article was merely cumulative, because it does not appear that any other reference disclosed a 99.2% pure lutein composition purified from marigolds. Moreover, the materiality of the article is not negated by the fact that the method disclosed therein may have required some modification in order to be operative. The article describes a composition that is likely within the scope of those claims, and is therefore prima facie material to patentability, irrespective of whether it was clear that the method disclosed in the article was fully operative.

We therefore conclude that PIVEG has raised substantial questions with respect to both the

validity and enforceability of the '714 patent, and it is not clear from the present record that Kemin has demonstrated that those questions lack substantial merit. Because a party moving for a preliminary injunction must show not only that it will likely prove infringement at trial, but also that the challenges to the validity and enforceability of its patent lack substantial merit, Anton/Bauer, 329 F.3d at 1348, and Kemin has not done so in this case, PIVEG's challenges provide an alternative ground for our holding that Kemin has not demonstrated the requisite likelihood of success on the merits required to sustain a preliminary injunction.

CONCLUSION

Because the district court erred in its construction of claims 1, 2, and 4 of the '714 patent and in its evaluation of the validity and enforceability of the patent, and thus seriously misjudged Kemin's likelihood of success on the merits of its case, we reverse the grant of preliminary injunction.

[1] Although the above discussion focuses on claim 1 of the '714 patent, our construction of the terms of that claim apply as well to claims 2 and 4, both of which depend from claim 1.

[2] To be sure, the district court also correctly stated that “[u]nder 35 U.S.C. § 102, a claim is anticipated, and therefore invalid, when a single prior art reference discloses each and every element of the claimed invention,” and that “if the prior art reference fails to suggest even one limitation of the claimed invention, then the claim is not anticipated.” Preliminary Order, 240 F. Supp. 2d at 969 (citing Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715 (Fed. Cir. 1984), and Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1574 (Fed. Cir. 1984)). The court then set forth PIVEG's and Kemin's respective arguments. However, the court did not follow its exposition of the law and the parties' arguments with any analysis of the invalidity question, immediately turning instead to PIVEG's “unenforceability defense,” see id. at 972.