

United States Court of Appeals for the Federal Circuit

05-1479, -1480

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

Plaintiffs-Cross Appellants,

v.

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

Defendant-Appellant.

06-1002

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

Plaintiffs-Appellees,

v.

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

Defendant-Appellant.

Susan K. Knoll, Howrey LLP, of Houston, Texas, argued for Kemin Foods, L.C., et al. With her on the brief were Richard L. Stanley and Scott W. Clark.

Michael A. Dee, Brown, Winick, Graves, Gross, Baskerville and Schoenebaum, PLC, of West Des Moines, Iowa, argued for PIGMENTOS VEGETALES DEL CENTRO S.A. DE C.V. With him on the brief was Camille L. Urban.

Appealed from: United States District Court for the Southern District of Iowa

Judge James E. Gritzner

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DECIDED: September 25, 2006

Before NEWMAN, MAYER, and BRYSON, Circuit Judges.

BRYSON, Circuit Judge.

I. Background

This litigation began when Kemin Foods, L.C., and The Catholic University of America filed a patent infringement suit against Pigmentos Vegetales del Centro S.A. de C.V. (“PIVEG”), alleging infringement of two patents. PIVEG counterclaimed, seeking a declaratory judgment that the two patents were invalid and unenforceable. PIVEG also filed counterclaims alleging unfair competition and antitrust violations. The unfair competition and antitrust counterclaims were severed from the remainder of the case, and the second case was stayed pending resolution of the patent issues.

Kemin Foods is the assignee of one of the two patents in suit, U.S. Patent No. 5,648,564 (“the ’564 patent”). The Catholic University of America owns the other patent, U.S. Patent No. 5,382,714 (“the ’714 patent”), and Kemin Foods is the exclusive licensee of that patent. (We refer to The Catholic University of America and Kemin Foods collectively as “Kemin.”) The patents in suit include process and product claims pertaining to purified lutein that is extracted from plants. Lutein is a carotenoid (i.e., an organic, naturally occurring pigment) that Kemin and PIVEG incorporate in dietary health supplements that they manufacture and distribute.

At trial, Kemin argued that PIVEG infringed product claims 1, 2, and 4 of the ’714 patent and process claim 1 of the ’564 patent. Kemin also intended to pursue an allegation of infringement of process claim 5 of the ’714 patent, but was effectively precluded from doing so by a pretrial order striking a supplemental expert report proffered by Kemin.

At the end of the trial, the jury found that the asserted claims were not invalid. The jury also found that the asserted claims of the ’714 patent were not infringed, but

that claim 1 of the '564 patent was infringed under the doctrine of equivalents. The jury awarded Kemin \$58,775 in damages. The district court denied the parties' respective motions for judgment as a matter of law, upheld the jury's verdicts on validity and infringement, and enjoined PIVEG from infringing the '564 patent. The court also rejected PIVEG's claim that both patents were unenforceable because of inequitable conduct. With respect to the '564 patent, the court concluded that Kemin did not withhold any material reference or intend to deceive the Patent and Trademark Office ("PTO"). With respect to the '714 patent, the court concluded that the showings of materiality and deceptive intent with respect to a reference withheld during prosecution were not sufficient to render the patent unenforceable. Finally, the district court determined that Kemin was the prevailing party in the patent portion of this suit, and it granted Kemin's request for an award of costs.

In appeal No. 05-1479, PIVEG challenges the portions of the court's judgment holding the '714 patent nonobvious, holding both patents enforceable, and awarding costs to Kemin. On those issues, we affirm. In its cross-appeal, No. 05-1480, Kemin challenges the court's judgment that the asserted claims of the '714 patent were not infringed. We affirm that ruling. Kemin also challenges the court's pretrial order striking Kemin's supplemental expert report. On that issue, we vacate and remand for the district court to consider the supplemental expert report and Kemin's claim of infringement of claim 5 of the '714 patent. Finally, Kemin asks that we modify the permanent injunction issued by the district court. We decline to do so and thus affirm the court's injunctive order.

Also before the court is PIVEG's separate appeal, No. 06-1002, from a decision in the severed portion of the litigation in which the court dismissed PIVEG's unfair competition and antitrust counterclaims and denied PIVEG leave to amend and supplement those counterclaims. On that appeal, we affirm.

II. PIVEG's Appeal in the Patent Case

A. Obviousness of Claim 1 of the '714 Patent

PIVEG argues that a prior art reference, a 1991 article in the journal Poultry Science, teaches all the limitations of claim 1 of the '714 patent except for the limitation requiring that the claimed purified lutein product contain no traces of toxic chemicals. With respect to that limitation, PIVEG argues that a person of ordinary skill in the art in the early 1990s would have known how to remove toxic solvents from purified lutein and would have been motivated to do so. PIVEG therefore contends that claim 1 would have been obvious in light of the disclosure in the Poultry Science article.¹

The problem facing PIVEG on appeal is that the jury concluded that PIVEG failed to meet its burden of proving by clear and convincing evidence that claim 1 would have been obvious. PIVEG's appeal is predicated entirely on the asserted insufficiency of the evidence to support the jury's verdict. We agree with the district court that substantial

¹ PIVEG also appears to contend that claim 1 would have been obvious in light of the Poultry Science article in combination with another reference, the Kuzmicky article. However, PIVEG failed to raise that argument in its post-trial motion for judgment as a matter of law, so we decline to consider it on appeal. See Bidex Corp. v. Loredan Biomedical, Inc., 946 F.2d 850, 862 (Fed. Cir. 1991) (refusing to review the sufficiency of the evidence supporting a jury verdict unless the alleged deficiency is first raised in some post-trial motion in the district court); see also Motorola, Inc. v. Interdigital Tech. Corp., 121 F.3d 1461, 1471 (Fed. Cir. 1997) ("ITC did not raise this argument in its post-trial motions before the district court. This court's consideration of objections first lodged on appeal is severely restricted.").

evidence supported the verdict, and we therefore affirm the judgment with respect to the claim of obviousness.²

The method of obtaining purified lutein disclosed in the Poultry Science article uses toluene as a solvent. The resulting “purified” lutein product contains some residual toluene. Both PIVEG and Kemin presented expert testimony on whether one of skill in the art could remove the toluene from the purified lutein. Kemin’s expert explained the difficulties with removing toluene from purified lutein crystals and testified that, although various separation methods would remove some of the toluene, those methods would not remove all traces of the toluene, as required by claim 1. In light of that testimony, it was reasonable for the jury to conclude that the claimed invention would not have been rendered obvious by what the Poultry Science article would have taught to a person of ordinary skill in the art at the time.

Kemin also presented evidence that the lutein obtained by the method disclosed in the Poultry Science article would not have satisfied two other requirements of claim 1 of the '714 patent as construed: that the lutein be “greater than about 90% pure” and that it contain “significantly less than 10% of other carotenoids.” Although PIVEG’s experts disputed some aspects of Kemin’s evidence, PIVEG has failed to show that no reasonable juror could have accepted Kemin’s version of the disputed facts.

² PIVEG argues that the substantial evidence standard should apply to our review of a jury’s obviousness finding only when we are reviewing special verdicts or jury interrogatories, and not when we are reviewing a general verdict. Our cases, however, have applied the substantial evidence standard to general jury verdicts on obviousness, see NPF Ltd. v. Smart Parts, Inc., No. 05-1273, slip op. at 4-5 (Fed. Cir. June 27, 2006); McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1350, 1356 (Fed. Cir. 2001), and PIVEG has not pointed to any contrary authority.

B. Enforceability of the '714 Patent

PIVEG next argues that the '714 patent should be held unenforceable for inequitable conduct. PIVEG's theory of inequitable conduct focuses on Dr. Christopher Nelson, who was the president of Kemin Foods during prosecution of the '714 patent. Although Dr. Nelson was not a named inventor on the '714 patent, he had previously been involved with Kemin's research on purified lutein. PIVEG's theory is that Dr. Nelson knew the Poultry Science article was material, that he was sufficiently involved in prosecution of the '714 patent to have a duty to disclose the reference, and that he withheld the article from the PTO with deceptive intent. In response to special interrogatories posed by the district court judge, the jury, acting in an advisory capacity, found that the Poultry Science article was material to the patentability of the '714 patent and that Dr. Nelson withheld the article with intent to deceive the PTO. Although the court did not reject the jury's findings, it "ultimately conclude[d] the levels of materiality and intent are not so high as to warrant a finding of culpable intent such that the '714 patent should be held unenforceable." PIVEG argues that the court erred by finding the levels of materiality and intent low, and that the court abused its discretion by refusing to hold the '714 patent unenforceable.

With respect to materiality, the court concluded that the Poultry Science article was not highly material. The court first held that the Poultry Science article did not render the patent invalid. It further noted that the evidence of record suggested that the method disclosed in the Poultry Science article may not work as intended. Relying on Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551 (Fed. Cir. 1989), PIVEG argues that materiality is not "negated" simply because the method disclosed in

the Poultry Science article required some modification in order to be operative. While that general principle is true, the district court did not hold that the Poultry Science article was immaterial because it was not enabled. The court agreed with PIVEG that the article was material; it simply disagreed that the article was “highly” material, because “the ability to duplicate the information disclosed is relevant to the level of materiality attached to that information,” and because there was “little persuasive record evidence the method disclosed [in the Poultry Science article] actually produces the composition disclosed.” The district court was thus “unpersuaded disclosure of the article would have had any significant impact on the ’714 patent.”

PIVEG has not pointed to any particular evidence or made any argument that would compel a finding of “high” materiality. See, e.g., Purdue Pharma L.P. v. Endo Pharm. Inc., 438 F.3d 1123, 1133 (Fed. Cir. 2006) (“Th[e] omission of information was material, but not as material as an affirmative misrepresentation would have been.”); PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1321 (Fed. Cir. 2000) (“There can be no doubt that . . . intentional ‘misrepresentations, omissions and half-truths to the PTO,’ made as a ‘persistent course’ of conduct, are highly material.”); Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 31 (Fed. Cir. 1999) (fact that claimed invention was developed as an improvement over a prior art patent supported finding that the prior art patent was “highly” material). Accordingly, we see no clear error in the district court’s finding as to the level of materiality of the Poultry Science article.

With respect to the issue of intent, the district court noted that the evidence of intent to deceive was “tenuous” and that the jury’s conclusion on that prong of

inequitable conduct was “reached on a shallow basis.” Dr. Nelson testified that he did not believe the Poultry Science article was relevant to the prosecution of the ’714 patent, because the ’714 patent was directed to lutein fit for human consumption and the Poultry Science article did not contemplate preparing lutein for that purpose. In Dr. Nelson’s view, the Poultry Science article was just “another paper that made crystals of lutein that nobody could eat.” In light of the difficulties associated with removing toxic chemicals from lutein—a step that would be required before humans could consume the lutein obtained by the method described in the Poultry Science article—the district court concluded that Dr. Nelson’s testimony provided a plausible explanation for his belief that the article was not material.

PIVEG’s evidence at trial focused on the fact that Dr. Nelson had previously experimented with the method described in the Poultry Science article. From that fact, PIVEG asked the district court to infer that Dr. Nelson acted with deceptive intent when he did not bring the article to the attention of the named inventors or the prosecuting attorneys so that they could disclose it to the PTO. The district court noted, however, that Dr. Nelson was only tangentially involved in prosecution of the ’714 patent and that more than two years had passed between the time Dr. Nelson experimented with the method of the Poultry Science article and the time of the ’714 prosecution. Because those facts can reasonably be viewed as militating against a finding of deceptive intent, we see no error in the district court’s conclusion that PIVEG did not make a strong showing of intent to deceive the PTO.

Even when a court finds that the patentee failed to disclose material information to the PTO and acted with deceptive intent, the court retains discretion to decide

whether the patentee's conduct is sufficiently culpable to render the patent unenforceable. See Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1359, 1372 (Fed. Cir. 2003) ("[A]n important step in the judicial resolution of inequitable conduct claims is for the court to determine whether the material misrepresentations or omissions in question are sufficiently serious in light of the evidence of intent to deceive, under all the circumstances, to warrant the severe sanction of holding the patent unenforceable. That determination is committed to the trial court's discretion."). In light of the district court's findings that the Poultry Science article was not highly material and that the showing of deceptive intent was not compelling, the court did not abuse its discretion when it declined to hold the '714 patent unenforceable.

C. Enforceability of the '564 Patent

PIVEG also argues that the '564 patent should be held unenforceable for inequitable conduct. The '564 patent claims a process for producing lutein crystals. One of the steps of the claimed process calls for the use of propylene glycol in a saponification reaction. During prosecution of the patent, Kemin did not disclose to the PTO that it and others in the industry had previously used propylene glycol to produce various poultry pigments. PIVEG argues that those prior uses of propylene glycol were material to the patentability of the '564 patent and that Kemin acted with deceptive intent when it failed to disclose those prior uses to the PTO. In response to special interrogatories, the jury found that the prior uses of propylene glycol processes were not material to patentability, and it found that Kemin did not withhold evidence of those prior uses with intent to deceive the PTO. The district court agreed with the jury's advisory

verdict, concluding that “there is a dearth of evidence to support [PIVEG’s] arguments of inequitable conduct related to the ’564 patent.”

Kemin does not dispute that before the filing of the ’564 patent application Kemin’s employees used propylene glycol to produce other poultry pigment products. Nor does Kemin appear to dispute that those other products may have contained carotenoid crystals. However, Kemin presented evidence that at the time of the ’564 patent prosecution, no one knew that propylene glycol processes were producing lutein crystals. Although Dr. Rodney Ausich, one of the named inventors on the ’564 patent, testified that he had observed crystals resulting from saponification using propylene glycol, he also testified that he “had no idea what chemical entity those crystals were” and that he had never seen “anything anywhere indicating that [the products], in fact, included crystals of any xanthophyll, much less lutein.” He further testified that despite a “long history of use of propylene glycol in Kemin and in the entire industry, . . . no one had recognized that you could simply add propylene glycol base and marigold oleoresin to create crystals like we were able to create.” That testimony supports the inference that there would have been no reason for anyone at Kemin to recognize that prior uses of propylene glycol in the poultry pigment industry were material to patentability. The district court therefore did not err in rejecting the claim of inequitable conduct in the prosecution of the ’564 patent.

D. The Award of Costs

Following the entry of judgment on the patent issues, PIVEG and Kemin each filed a bill of costs, each asserting that it was the prevailing party in the litigation and thus entitled to costs under Federal Rule of Civil Procedure 54(d). The district court

held that Kemin was the prevailing party because Kemin prevailed on one of its two infringement claims (resulting in a damages award and a permanent injunction) and because Kemin prevailed on PIVEG's invalidity and unenforceability claims.

PIVEG argues that the district court erred by declaring Kemin the prevailing party in this litigation. PIVEG first points out that Kemin prevailed on only one of its two infringement claims. The fact that a party does not prevail on all of its claims does not, however, preclude it from being the prevailing party for purposes of awarding costs under Rule 54(d). See, e.g., Manildra Milling Corp. v. Ogilvie Mills, Inc., 76 F.3d 1178, 1183 (Fed. Cir. 1996) (holding that the plaintiff prevailed for purposes of Rule 54(d) when it successfully challenged the validity of its opponent's patent, even though the plaintiff lost on its antitrust and unfair competition claims).

PIVEG argues that it should be considered the prevailing party because its behavior was not affected by the permanent injunction issued in this case, since during the litigation PIVEG switched to a non-propylene-glycol process that was outside the scope of the injunction. Notwithstanding PIVEG's purported alteration of its process, an injunction issued based on the court's conclusion that PIVEG had infringed the '564 patent, and the consequence of the injunction was to prohibit PIVEG from using the process described in the '564 patent. PIVEG also argues that it prevailed in the litigation because the jury found that it "successfully established the elements of inequitable conduct as to the '714 patent by clear and convincing evidence." That argument ignores the fact that PIVEG ultimately lost on its unenforceability claim.

Finally, PIVEG argues that the district court abused its discretion by awarding Kemin its full costs rather than apportioning costs according to the "relative success" of

the parties. Cost awards are committed to the discretion of the district courts, and there is no rule requiring courts to apportion costs according to the relative success of the parties. See Johnson v. Nordstrom-Larpenteur Agency, Inc., 623 F.2d 1279, 1282 (8th Cir. 1980) (“Where each of the parties has prevailed on one or more of its claims, defense or counterclaims, the district court has broad discretion in taxing costs.”). In fact, apportioning costs according to the relative success of parties is appropriate only under limited circumstances, such as when the costs incurred are greatly disproportionate to the relief obtained. See 10 James Wm. Moore et al., Moore’s Federal Practice § 54.101[1][b] (3d ed. 2006). The present case does not present such circumstances, so we cannot say that the district court abused its discretion by declining to apportion costs. While PIVEG prevailed on some issues, we conclude that on the whole Kemin’s success in the litigation was sufficiently clear that the district court did not abuse its discretion in ruling that Kemin was the prevailing party and declining to apportion costs.

III. Kemin’s Cross-Appeal in the Patent Case

A. Infringement of the '714 Patent

Kemin challenges the jury’s verdict of noninfringement of claims 1, 2, and 4 of the '714 patent. Claims 2 and 4 are dependent on claim 1, and Kemin’s appeal focuses on whether PIVEG’s products meet three disputed limitations of claim 1. We conclude that the jury could reasonably have concluded that the accused products do not meet two of those limitations, and so we affirm the judgment of noninfringement.

Claim 1 of the '714 patent reads:

The carotenoid composition consisting essentially of substantially pure lutein crystals derived from plant extracts that contain lutein . . .

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

On a previous appeal from the district court's grant of a preliminary injunction, we preliminarily construed the disputed limitations of claim 1. Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V., 93 Fed. Appx. 225 (Fed. Cir. 2004). The district court subsequently adopted our preliminary construction of the claims for purposes of the jury trial on infringement. Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. de C.V., 319 F. Supp. 2d 939, 942-43 (S.D. Iowa 2004). Kemin does not challenge that claim construction. Rather, Kemin contends that no reasonable juror could have found that PIVEG's products fall outside the literal scope of the claim as construed. Whether a product falls within the literal scope of a properly construed claim is a question of fact, on which we accord a jury substantial deference. See PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1355 (Fed. Cir. 1998) ("[A]fter the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact."). Kemin also argues that even if PIVEG's products fall outside the literal scope of the claims, the products should be found to infringe under the doctrine of equivalents. Yet that too was a question of fact for the jury in this case. See, e.g., Interactive Pictures Corp. v. Infinite Pictures, Inc., 274 F.3d 1371, 1376 (Fed. Cir. 2001) ("Determination of infringement by equivalents is an issue of fact, which after a jury trial we review for substantial evidence. We will not disturb a jury finding of infringement by equivalents unless the evidence so favors the accused infringer that reasonable jurors

could not arrive at a contrary verdict." (citations, internal quotation marks, and brackets omitted)).

With respect to the limitation requiring the lutein composition to be "substantially free from other carotenoids . . . found in the natural form of lutein in the plant extract," we construed that limitation to require "significantly less than 10% of other carotenoids." Kemin Foods, 93 Fed. Appx. at 232. That construction was based in part on a passage in the specification noting that "[g]enerally, the concentration of other carotenoids in the starting material should be 10% or less." '714 patent, col. 3, ll. 57-59. We reasoned that "[i]f 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." 93 Fed. Appx. at 232.

On appeal, the parties disagree about the percentage of "other carotenoids" present in PIVEG's products. Both parties analyzed samples of those products and presented their analyses to the jury. In Kemin's view, the percentage of "other carotenoids" in PIVEG's products ranges from 6.14 to 9.86. In PIVEG's view, the percentage of "other carotenoids" in its products is greater than 9 and as high as 14. Kemin has not argued that the phrase "significantly less than 10%" has a precise upper limit. Thus, the question whether the concentration of "other carotenoids" in PIVEG's products is low enough to infringe the '714 patent was properly left to the jury. As we have noted, "it is possible that under such circumstances different finders of fact could reach different conclusions. That possibility, however, is a necessary consequence of treating infringement as a question of fact subject to deferential review." PPG Indus.,

156 F.3d at 1355. Therefore, even if the jury accepted Kemin's carotenoid measurements, it could reasonably conclude that although PIVEG's products had less than 10% of other carotenoids, they did not have "significantly less than 10% of other carotenoids." Similarly, the jury could have concluded that the levels of other carotenoids in PIVEG's products were high enough that they were outside the scope of the doctrine of equivalents as applied to that limitation.

The jury also could have concluded that PIVEG's products do not satisfy claim 1's limitation on the presence of toxic chemicals in the lutein product. We previously construed claim 1 to require "no traces of toxic chemicals." Kemin Foods, 93 Fed. Appx. at 232. In reaching that conclusion, we pointed to language in the specification stating that "the purified lutein is required not to contain even traces of any toxic chemicals." Id. (quoting '714 patent, col. 4, ll. 16-17). It is undisputed that PIVEG's products contain some hexane, at levels as high as 23 parts per million. It also appears undisputed that hexane may be considered toxic even in very low concentrations. Kemin argues that chemicals are not inherently toxic or nontoxic, and that any chemical can be toxic in sufficient quantities. Thus, according to Kemin, toxicity has meaning only in reference to toxic amounts of a particular chemical. In Kemin's view, the phrase "no traces of toxic chemicals" simply requires that the product not contain any chemicals in an amount that would be toxic to a human.

The problem with Kemin's argument is that the '714 patent and our previous construction of claim 1 do not merely exclude toxic amounts of chemicals. Rather, the patent discusses particular chemicals as "toxic" and explains that in order to produce lutein for human consumption one must eliminate any amount of such chemicals from

the lutein product. For example, the patent suggests that methanol and isopropyl alcohol should not be used to produce the patented product because they are toxic. See '714 patent, col. 4, ll. 14-19 (“Instead of ethanol, other alcohols such as methanol or isopropyl alcohol may also be employed. However, since the purified lutein is required not to contain even traces of any toxic chemicals, the use of methanol instead of food grade ethanol in this purification process is not normally recommended.”). We construed claim 1 to require “no traces” of such chemicals.

Kemin’s argument, both at trial and on appeal, has been that the phrase “no traces of toxic chemicals” should be interpreted as limiting the claim to products in which the levels of all chemicals are below the toxic thresholds set by the Food and Drug Administration. Neither the patent nor our claim construction, however, makes any reference to toxicity thresholds, whether promulgated by the FDA or otherwise. Accordingly, it was not error for the district court not to instruct the jury in accordance with Kemin’s interpretation of the claim limitation. In light of our construction of the claim, the jury could reasonably have concluded that PIVEG’s products do not infringe, either literally or under the doctrine of equivalents, because they contain traces of toxic chemicals, even though the levels of those toxic chemicals may not be high enough to cause illness or death in humans.

B. Kemin’s Supplemental Expert Report

Kemin next argues that the magistrate judge erred by granting PIVEG’s motion to strike a supplemental expert report proffered by Kemin. The district court upheld the magistrate judge’s decision on that motion, with minimal comment. In Kemin’s view, the magistrate judge’s decision rested on erroneous grounds and prejudiced Kemin

because it prevented Kemin from asserting infringement of process claim 5 of the '714 patent. We agree with Kemin that it was an abuse of discretion to strike the supplemental expert report, and we agree that for that reason the issue of infringement of claim 5 of the '714 patent must be remanded to the district court.

In granting PIVEG's motion to strike, the magistrate judge admonished Kemin for the late timing of the "additional claim" raised by the supplemental expert report. The magistrate judge was referring to the fact that the report addressed infringement of process claim 5, a claim that the magistrate judge apparently believed was being raised in the supplemental expert report for the first time in the litigation. Thus, the magistrate judge treated Kemin's supplemental expert report as, in effect, a request by Kemin to amend its original complaint with an allegation that PIVEG infringed claim 5 of the '714 patent. However, the supplemental expert report was not such a request, either in fact or in effect.

In its original complaint, Kemin broadly alleged that PIVEG was infringing the '714 and '564 patents, "including without limitation claim 1" of both patents. That language in the complaint was sufficiently broad to encompass a charge of infringement of all the claims of the two patents. PIVEG has not pointed to anything in the record suggesting that Kemin narrowed the scope of its complaint at any time prior to the December 22, 2003, supplemental expert report. To the contrary, it appears that Kemin diligently pursued discovery to ascertain whether PIVEG's process implicated claim 5 and kept the court and PIVEG on notice that claim 5 might be asserted at trial. For example, in response to an interrogatory asking which claims Kemin was alleging were infringed, Kemin listed claims 1, 2, and 4 of the '714 patent and claim 1 of the '564

patent, but it noted that PIVEG “has yet to produce its process for producing lutein crystal products . . . so Plaintiffs reserve the right to seasonably update this response as the discovery may reveal that other patent claims are also infringed.” Also, in Markman briefing Kemin noted that preliminary analysis of PIVEG’s products revealed the presence of residual propylene glycol, suggesting that PIVEG’s process for producing purified lutein infringes process claim 1 of the ’564 patent. However, Kemin noted:

To date . . . discovery regarding PIVEG’s actual process has been unreliable at best and is the subject of a motion to compel by Kemin. Thus, it is possible that PIVEG may use a water/alcohol mixture, as the solvent in its process, thereby infringing the method of claim 5 of the ’714 patent. Accordingly, as discovery is ongoing, Kemin reserves the right to assert claim 5 of the ’714 patent when PIVEG’s process is known. There are no additional claim construction issues that arises [sic] with respect to claim 5 of the ’714 patent which are not already addressed [by the briefing on the claims already specifically asserted].

As those passages suggest, Kemin had difficulty obtaining information about PIVEG’s process. Pursuant to a corporate policy, PIVEG maintained no documentation of its process for purifying lutein. The only such documentary evidence PIVEG provided Kemin was a two-page document prepared at the request of PIVEG’s litigation counsel. As part of discovery, Kemin was permitted to visit PIVEG’s manufacturing facility—which is located in Mexico—in July 2003. When Kemin visited the facility, however, various parts of PIVEG’s process were either not operating at all or were not operating under normal conditions. As a result, the district court ordered a second inspection, which occurred on November 14 and 15, 2003. The site visits suggested some inconsistencies between PIVEG’s actual process and its two-page process document. As Kemin’s supplemental expert report explained, analysis of samples collected during the second visit suggested—for the first time—that PIVEG’s process might be covered

by claim 5 of the '714 patent. The supplemental expert report was filed with the district court on December 22, 2003, one day before the deadline set by the magistrate judge.

We see nothing more Kemin could have done to keep claim 5 alive during the pretrial phase of the litigation. Kemin repeatedly advised the court and PIVEG that once it obtained information about PIVEG's process, that information might implicate claim 5. In the Markman briefing, Kemin took account of claim 5. And as soon as it obtained sufficient information about PIVEG's process, Kemin provided a detailed analysis of its claim 5 infringement contentions. Under these circumstances, we conclude that the magistrate judge should not have granted PIVEG's motion to strike Kemin's supplemental expert report.

Because the supplemental expert report was the primary—perhaps even the sole—evidentiary basis for Kemin's claim 5 infringement allegation, the effect of the magistrate's decision was to preclude Kemin from pursuing its allegation of infringement of claim 5. That outcome is potentially significant, because in order to avoid the effect of the '564 patent injunction, PIVEG asserts that it has switched to a new process. Yet according to Kemin, even if that process falls outside the injunction, it still might infringe claim 5 of the '714 patent. Thus, we vacate the judgment as it applies to claim 5 of the '714 patent, and we remand for the district court to consider Kemin's supplemental expert report and Kemin's related allegation that PIVEG infringes claim 5 of the '714 patent.

C. Modifying the Permanent Injunction

Kemin also argues that we should modify the terms of the permanent injunction to cover "all processes run by [PIVEG] at any time through the date of the jury's verdict."

In Kemin's view, such a modification is necessary to ensure that the injunction provides meaningful relief. We disagree.

On January 24, 2004, PIVEG notified Kemin that it had modified its purified lutein process from what Kemin had observed just months earlier during its second visit to PIVEG's manufacturing facility. In response, Kemin requested that the district court apply 35 U.S.C. § 295 and thereby shift the burden of proof to PIVEG with respect to the claim of infringement of process claim 1 of the '564 patent. The district court granted Kemin's motion in August 2004. In Kemin's view, the effect of section 295 in this case should be to impose on PIVEG the burden of proving noninfringement with respect to every purified lutein process PIVEG used through the end of trial.

The problem with that argument is that the district court's decision to apply 35 U.S.C. § 295 was based in part on Kemin's showing of a substantial likelihood that the process PIVEG was using before November 2003 infringed claim 1 of the '564 patent. PIVEG claims that after November 2003 it switched to a process that does not use propylene glycol. Because the process claimed in the '564 patent requires propylene glycol, a non-propylene-glycol process would not infringe the '564 patent. Kemin argues, however, that a non-propylene-glycol process could infringe claim 5 of the '714 patent, since that claim does not require the use of propylene glycol. Whether PIVEG's modified process infringes claim 5 of the '714 patent is an open question for the district court to address on remand.

IV. PIVEG's Appeal on the Amended Counterclaims

In a separate appeal, No. 06-1002, PIVEG argues that the district court erred by denying its motion for leave to amend its severed counterclaims. We agree with the

district court that PIVEG's amended counterclaims were futile, and we therefore affirm the district court's denial of leave to amend.

Following trial on the patent infringement issues, Kemin moved to dismiss PIVEG's counterclaims alleging unfair competition and antitrust violations. Kemin argued that those counterclaims hinged on PIVEG's claims of patent unenforceability and invalidity, and therefore that the district court's judgment holding the patents enforceable and not invalid foreclosed the counterclaims.

In response, PIVEG moved to amend and supplement its counterclaims. PIVEG's amended counterclaims were counterclaim III, alleging unfair competition, and counterclaim IV, alleging antitrust violations based on fraudulent procurement of a patent. PIVEG's new counterclaims were counterclaim V, alleging antitrust violations based on sham litigation; counterclaim VI, alleging antitrust violations based on patent misuse; and counterclaim VII, alleging false marking of products in violation of 35 U.S.C. § 292.³

The district court dismissed PIVEG's original counterclaims and denied PIVEG's motion for leave to amend and supplement its counterclaims. PIVEG has not appealed the district court's dismissal of its original counterclaims, and it concedes on appeal that proposed counterclaims IV and V hinge on the unenforceability of the patents. In light of our conclusion on the issue of unenforceability, we need not address counterclaims IV and V. What remains for us to consider is whether the district court erred by denying leave to amend counterclaim III (unfair competition) and to add counterclaims VI

³ Counterclaims I and II sought declarations of invalidity and unenforceability of the '714 and '564 patents and were therefore mooted by the patent judgment.

(antitrust based on patent misuse) and VII (false marking). We conclude that the court did not err.

Federal Rule of Civil Procedure 15(a) provides that leave to amend “shall be freely given when justice so requires.” Nonetheless, leave to amend may be denied if the court finds that there has been undue delay that would prejudice the nonmoving party, that the moving party has acted in bad faith, or that the amendment would be futile. See, e.g., Foman v. Davis, 371 U.S. 178, 182 (1962). The timing of PIVEG’s motion for leave to amend also implicates Federal Rule of Civil Procedure 16, because PIVEG’s motion came nearly two years after the deadline for amended pleadings specified in the district court’s scheduling order. Once a deadline set by a district court’s scheduling order has passed, Rule 16(b) requires a party to show good cause before being granted leave to amend. See, e.g., In re Milk Prods. Antitrust Litig., 95 F.3d 430, 437-38 (8th Cir. 1999). Even when such a showing is made, the district court may exercise its discretion to refuse to allow the amendment. See, e.g., Bradford v. DANA Corp., 249 F.3d 807, 809 (8th Cir. 2001).

The district court held that PIVEG’s proposed counterclaims were futile, and it based its ruling in part on that ground. We uphold the court’s ruling on that basis. Like its original counterclaims, PIVEG’s proposed amended counterclaims hinge to a large extent on its assertion that Kemin’s patents are invalid or unenforceable. To that extent, PIVEG’s proposed counterclaims are foreclosed by the judgment as to invalidity and unenforceability. Only two aspects of PIVEG’s counterclaims do not turn on those issues. First, PIVEG argues that in light of the district court’s claim construction, Kemin’s own products are not covered by the ’714 patent. Thus, PIVEG argues that

Kemin has violated unfair competition laws, antitrust laws, and the false marking statute by continuing to represent to the public and competitors that its products are covered by the '714 patent. Second, PIVEG argues that Kemin has known since January 2004 that PIVEG is no longer using propylene glycol in its process for producing purified lutein. Thus, PIVEG argues that Kemin has engaged in unfair competition and antitrust violations by continuing to represent to the public and competitors that PIVEG is infringing the '564 patent.⁴

We agree with PIVEG that those aspects of its amended counterclaims are not legally foreclosed by the resolution of the patent issues in the “patent phase” of the case. The unfair competition and antitrust counterclaims are separate claims that were severed by the court early in the case, and Kemin cites no persuasive authority for the proposition that PIVEG was required to present the allegations of false marking and false assertions of infringement in the patent phase of the case or risk forfeiting its separate claims of unfair competition and antitrust violations based on similar allegations.

⁴ As part of its unfair competition counterclaim, PIVEG also alleged that Kemin exploited the knowledge of a former PIVEG employee in violation of a nondisclosure agreement between PIVEG and that employee. The district court found that allegation to be untimely and the delay to be prejudicial to Kemin, based on its finding that PIVEG knew the pertinent facts about the alleged violation of the nondisclosure agreement long before it moved to amend. Although PIVEG has reproduced the text of the amended counterclaim in its brief, including the allegation about the nondisclosure agreement, it has not addressed the district court’s specific ruling with respect to that allegation, and we conclude that PIVEG has waived that claim for purposes of appeal. In any event, to the extent that PIVEG’s general argument regarding untimeliness and prejudice are directed to that aspect of the district court’s decision, we hold that PIVEG’s argument does not provide a sufficient basis to overturn the court’s finding on that issue.

The district court's decision not to permit amendment of the counterclaims was based in part on the court's conclusion that PIVEG had made the same arguments regarding patent misuse and false marking during the patent phase of the case and that it would be improper to give PIVEG another opportunity to make the same arguments. PIVEG, however, contends that it never raised those issues in the patent phase of the case, and Kemin concedes that PIVEG is correct on that point. That aspect of the court's ruling therefore cannot serve as a valid ground for its decision.

The district court also ruled that PIVEG had failed to plead all of the elements necessary for its unfair competition claim. We disagree. The allegations in PIVEG's proposed counterclaim III address each of the elements of an unfair competition claim under the Lanham Act, 15 U.S.C. § 1125(a). See Zenith Elecs. Corp. v. Exzec, Inc., 182 F.3d 1340, 1348 (Fed. Cir. 1999). PIVEG's proposed counterclaim III was therefore sufficient to assert a Lanham Act violation.

While some of the grounds invoked by the district court do not support its order, the district court went further and ruled that PIVEG "has not demonstrated that [its] proposed counterclaims are not futile beyond making, without support, a [bare] assertion that its amended counterclaims meet the pleading requirements." We agree with the court that the three counterclaims at issue are futile under the applicable standard.

When a party faces the possibility of being denied leave to amend on the ground of futility, that party must demonstrate that its pleading states a claim on which relief could be granted, and it must proffer sufficient facts supporting the amended pleading that the claim could survive a dispositive pretrial motion. See, e.g., Norbeck v.

Davenport Cnty. Sch. Dist., 545 F.2d 63, 70 (8th Cir. 1976) (concluding that the district court did not abuse its discretion in denying a request to amend the complaint where the amendment would not have remedied deficiencies in the complaint); Wilson v. Am. Trans Air, Inc., 874 F.2d 386, 392 (7th Cir. 1989) (“An amendment is a ‘futile gesture’ if the amended pleading could not survive a motion for summary judgment”; the moving party must do more than offer a “conclusory suggestion that additional discovery might turn something up that would support” the new claim.). Although PIVEG had ample opportunity to defend the sufficiency of its proposed counterclaims and to point to facts in the record supporting its revised counterclaims, it made no attempt to do so. Rather, PIVEG responded to Kemin’s challenges merely by asserting—without elaboration—that its proposed counterclaims met the liberal standard of notice pleading.

On the record before it, the district court was justified in concluding that the proposed counterclaims were futile. As noted, the two grounds that PIVEG invokes to support counterclaims III, VI, and VII are Kemin’s alleged false marking of its products with the ’714 patent number and Kemin’s assertion that PIVEG’s products infringe the ’564 patent. With respect to the false marking issue, Kemin has maintained throughout the litigation, including in its cross-appeal presently before us, that claim 1 of the ’714 patent is broad enough to encompass PIVEG’s products (and thus also its own commercial lutein products). Moreover, neither the district court nor this court has held that Kemin’s products are outside the scope of the ’714 patent. Kemin’s legal position as to the scope of the ’714 patent is sufficiently plausible that Kemin cannot be said to have acted with the deceptive purpose necessary to trigger liability under the false

marking statute (or, derivatively, to form the basis for an antitrust or Lanham Act claim).

See Clontech Labs., Inc. v. Invitrogen Corp., 406 F.3d 1347, 1351-55 (Fed. Cir. 2005).

With respect to the issue of the false assertion of infringement, PIVEG argues that after it advised Kemin that it had changed its process and had begun making lutein without propylene glycol, it became indisputably clear that PIVEG no longer infringed the '564 patent. According to PIVEG, Kemin therefore engaged in patent misuse (and, derivatively, violations of the Lanham Act and the Sherman Act, 15 U.S.C. § 2) when it advised third parties that PIVEG was still infringing the '564 patent.

The district court addressed that issue in its May 9, 2005, order in which the court discussed the formulation of the permanent injunction that the court issued in this case. The court explained that PIVEG “did not irrefutably prove that it modified its process in any significant way, much less that said modified process did not use propylene glycol in any manner.” In light of that finding, it is not indisputable that PIVEG’s modified process omits the use of propylene glycol and therefore that PIVEG necessarily ceased infringing the '564 patent in November 2003. A patentee in Kemin’s position is entitled to assert that an accused product infringes its patent, “unless [an opponent] can show that the patent holder acted in bad faith.” Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1336 (Fed. Cir. 1998); see also Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 709 (Fed. Cir. 1992) (patent holder “that has a good faith belief that its patents are being infringed violates no protected right when it so notifies infringers”). In the absence of any challenge by PIVEG to the district court’s characterization of the record, and in the absence of any effort by PIVEG to supplement its showing as to the force of its allegations regarding the '564 patent, we uphold the

district court's characterization of those allegations in the unfair competition and antitrust counterclaims as futile. We therefore affirm the district court's order denying leave to amend the counterclaims.

V. Conclusion

In summary, we affirm the district court's judgment in No. 05-1479 in all respects; we affirm the judgment in No. 05-1480, except as to Kemin's claim that the court should not have excluded its expert's supplemental report, which formed the basis for its infringement allegations as to claim 5 of the '714 patent; and we affirm the judgment in No. 06-1002 in all respects.

Each party shall bear its own costs for this appeal.

AFFIRMED IN PART, VACATED IN PART and REMANDED.