

370 F.3d 1354

METABOLITE LABORATORIES, INC. and
Competitive Technologies, Inc., Plaintiffs-Appellees,

v.

LABORATORY CORPORATION OF AMERICA
HOLDINGS (doing business as LabCorp), Defendant-
Appellant.

No. 03-1120.

United States Court of Appeals, Federal Circuit.

DECIDED: June 8, 2004.

COPYRIGHT MATERIAL OMITTED COPYRIGTH MATERIAL OMITTED Glenn K. Beaton, Gibson, Dunn & Crutcher LLP, of Denver, CO, argued for plaintiffs-appellees. With him on the brief were J. Gregory Whitehair and Amanda J. Tessar. Also on the brief was Mark A. Perry, of Washington, DC.

Jonathan S. Franklin, Hogan & Hartson L.L.P., of Washington, DC, argued for defendant-appellant. With him on the brief was Catherine E. Stetson. Of counsel on the brief was John P. Higgins, Alston & Bird, LLP, of Charlotte, North Carolina.

Before RADER, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and SCHALL, Circuit Judge.

Opinion for the court filed by Circuit Judge RADER, dissenting-in-part and concurring-in-part opinion filed by Circuit Judge SCHALL.

RADER, Circuit Judge.

1

In the United States District Court for the District of Colorado, a jury found that Laboratory Corporation (LabCorp) indirectly infringed Metabolite Laboratories, Inc.'s (Metabolite's) U.S. Patent No. 4,940,658 (the '658 patent). The jury also found that LabCorp partially breached its contract with Metabolite. Based on this verdict, the district court assessed damages of \$3,652,724.61 for breach of contract and \$1,019,365.01 for indirect infringement. *Metabolite Labs., Inc. v. Lab. Corp.*, No. 99-Z-870 (D.Colo. Dec. 3, 2001). After denying LabCorp's motion for judgment as a matter of law (JMOL), the district court doubled the infringement award for willful infringement and issued a permanent injunction. *Metabolite Labs., Inc. v. Lab. Corp.*, No. 99-Z-870 (D.Colo. Nov. 19, 2001). Because the record supports the jury's verdicts and the trial court's decisions, this court affirms.

I.

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The '658 patent claims methods for detecting cobalamin or folate deficiency. Cobalamin and folate are both B vitamins, commonly known as B₁₂ and folic acid, respectively. A deficiency in these vitamins can cause serious illnesses in humans, including vascular disease, cognitive dysfunction, birth defects and cancer. If detected early enough, however, vitamin supplements readily treat the deficiency.

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Because these B vitamins assist in metabolizing the amino acid homocysteine, scientists directly assayed homocysteine to screen for cobalamin and folate deficiency. These direct homocysteine assays were unreliable. Then researchers at University Patents Inc. (UPI) discovered a relationship between elevated levels of total homocysteine and a deficiency in either cobalamin or folate. The total homocysteine test, however, could not alone identify which vitamin was deficient. Total homocysteine includes free and protein-complexed homocysteine and also includes homocysteine derivatives homocystine and homocysteine-cysteine.

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Originally, doctors could not conveniently treat both deficiencies because while folate was available in tablet form, cobalamin could only be administered by injection. After cobalamin became available in tablet form, however, doctors could simply order a total homocysteine test and, without identifying the deficient vitamin, treat elevated levels of total homocysteine with a tablet containing both cobalamin and folate. The UPI inventors also developed a test to identify the deficient vitamin using methylmalonic acid (the panel test method). The '658 patent claims both the total homocysteine test and the total homocysteine-methylmalonic acid test.

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Claim 13 claims the total homocysteine test:

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13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:

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assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

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'658 patent, col. 11, ll. 58-65.

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UPI's successor, Competitive Technologies Inc., licensed the patent to Metabolite, which in turn sublicensed the patent to Roche Biomedical Laboratories (now LabCorp). LabCorp, a laboratory testing company, originally performed total homocysteine assays under the sublicense. But in 1998, LabCorp switched to a total homocysteine assay developed by Abbott Laboratories (Abbott test) and discontinued royalty payments to Metabolite for total homocysteine assays.

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In response, Metabolite sued LabCorp for infringement. The district court construed the disputed claim terms, and the case proceeded to a jury. The jury found that LabCorp breached its license agreement with Metabolite, that LabCorp willfully infringed the '658 patent, and that the claims at issue are not invalid. The jury assessed damages against LabCorp of \$3,652,724.61

for breach of contract and \$1,019,365.01 for infringement. The district court entered judgment against LabCorp and awarded damages as assessed by the jury.

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After the trial, the district court denied LabCorp's motion for JMOL on infringement, breach of contract, invalidity, and willful infringement. In light of the finding of willfulness, the district court doubled the jury's infringement award to \$2,038,730.02. The district court also permanently enjoined LabCorp from using the homocysteine-only test. LabCorp appeals the district court's claim construction as well as the denial of JMOL.

II.

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Claim construction is a matter of law that this court reviews without deference. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed.Cir.1998) (en banc). The jury's finding of infringement, however, raises questions of fact, which this court reviews for substantial evidence. *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1348-49 (Fed.Cir.2000).

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This court reviews a denial of JMOL without deference by reapplying the JMOL standard. Thus, this court will affirm a denial of JMOL unless substantial evidence does not support the jury's factual findings or the verdict rests on legal errors. *Waner v. Ford Motor Co.*, 331 F.3d 851, 855 (Fed.Cir.2003).

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Whether a specification complies with the written description requirement of 35 U.S.C. § 112, paragraph 1, is a question of fact that this court reviews for substantial evidence. *Union Oil v. Atl. Richfield Co.*, 208 F.3d 989, 996 (Fed.Cir.2000). Enablement is a matter of law that this court reviews without deference; however, this court reviews the factual underpinnings of enablement for substantial evidence. *BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1371-72 (Fed.Cir.2003). Similarly, this court reviews the legal determination of obviousness without deference, but reviews its factual underpinnings for substantial evidence. *Teleflex, Inc. v. Ficoso N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed.Cir.2002). This court reviews a legal finding of indefiniteness without deference. *BJ Servs.*, 338 F.3d at 1371-72. Whether a prior art reference anticipates a patent is a factual determination that this court reviews for substantial evidence. *Teleflex*, 299 F.3d at 1323.

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Whether infringement was willful is a question of fact that this court reviews for substantial evidence. *Crystal Semiconductor Corp. v. TriTech Microelects. Int'l, Inc.*, 246 F.3d 1336, 1346 (Fed.Cir. 2001). This court reviews an award of enhanced damages and grant of a permanent injunction for abuse of discretion. *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1272 (Fed.Cir.1999).

III.

Infringement

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The primary challenge to the jury's indirect infringement verdict requires this court to review the district court's construction of the claim term "correlating." The infringement inquiry is a two-step process. This court construes the disputed claim terms and then compares the properly construed claims to the accused device. *Cybor Corp.*, 138 F.3d at 1454. Thus, this court first reviews the district court's claim construction.

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As always, the claim language itself governs its meaning. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). This court construes the meaning of claim language according to its usage and context. *ResQNet.com, Inc. v. Lansa, Inc.*, 346 F.3d 1374, 1378 (Fed.Cir.2003). The touchstone for discerning the usage of claim language is the understanding of those terms among artisans of ordinary skill in the relevant art at the time of invention. See *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed.Cir.2001). Indeed, normal rules of usage create a "heavy presumption" that claim terms carry their accustomed meaning in the relevant community at the relevant time. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed.Cir.2002) (citing *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed.Cir.1999)). Thus, this court sets the meaning of claim terms by ascertaining their technological and temporal context.

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In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention. In addition to providing contemporaneous technological context for defining claim terms, the patent applicant may also define a claim term in the specification "in a manner inconsistent with its ordinary meaning." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1347 (Fed.Cir.2003) (citing *Teleflex*, 299 F.3d at 1325-26). In other words, a patent applicant may define a term differently from its general usage in the relevant community, and thus expand or limit the scope of the term in the context of the patent claims. *Id.* Therefore, the primary aids to supply the context for interpretation of disputed claim terms are in the intrinsic record. *Vitronics*, 90 F.3d at 1582 (Fed.Cir.1996).

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Another tool to supply proper context for claim construction is the prosecution history. As in the case of the specification, the patent applicant's consistent usage of a term in prosecuting the patent may enlighten the meaning of that term. *Middleton, Inc. v. Minn. Mining & Mfg. Co.*, 311 F.3d 1384, 1388 (Fed.Cir.2002) (a patent applicant may "clearly and unambiguously" disavow claim scope during prosecution).

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This court also acknowledges the relevance of extrinsic evidence, often presented in the form of expert testimony. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed.Cir.1999) ("[C]onsultation of extrinsic evidence is particularly appropriate to ensure that [the court's] understanding of the technical aspects of the patent is not entirely at variance with

the understanding of one skilled in the art."); *Vitronics*, 90 F.3d at 1585. Another excellent source of context for disputed terms is dictionary definitions and treatises. *See, e.g., Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed.Cir.2002) ("[D]ictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms.").

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As noted before, these claim construction aids inform the court's task of ascertaining the meaning of the claim terms to one of ordinary skill in the art at the time of invention. *Moba v. Diamond Automation, Inc.*, 325 F.3d 1306, 1315 (Fed.Cir.2003) ("Moreover, as this court has repeatedly counseled, the best indicator of claim meaning is its usage in context as understood by one of skill in the art at the time of invention."); *Ferguson Beauregard v. Mega Sys., LLC*, 350 F.3d 1327, 1338 (Fed.Cir.2003) ("The words used in the claims must be considered in context and are examined through the viewing glass of a person skilled in the art."); *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1332 (Fed.Cir.2001) ("[I]t is important to bear in mind that the viewing glass through which the claims are construed is that of a person skilled in the art."); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 986 (Fed.Cir.1995) (en banc) ("[T]he focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean."). In this case, as evidenced by the jury instruction, the parties agreed that the level of ordinary skill in this field of invention was "a person having a medical degree and experience in researching the amino acid homocysteine and its relationship to diseases."

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The disputed term "correlating" appears in the second step of claim 13, which states: "[C]orrelating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." In its *Markman* brief below, LabCorp urged the district court to construe "correlate" according to its dictionary definition as a verb meaning "to establish a mutual or reciprocal relation of" an elevated level of homocysteine. LabCorp further argued that the district court should construe the "correlating" step as establishing that an elevated level of homocysteine is caused by a "shortage of cobalamin which causes a hematologic or neuropsychiatric abnormality," or "[a] deficiency of folate which causes a hematologic abnormality." The district court adopted LabCorp's dictionary definition by construing "correlating" to mean "to establish a mutual or reciprocal relationship between," but declined to "include a reference to hematologic or neuropsychiatric abnormality" in order to avoid impermissibly importing a limitation from the specification.

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On appeal, LabCorp argues that claim 13's correlating step should be construed as establishing that an elevated level of homocysteine is caused by a "shortage of cobalamin which causes a hematologic or neuropsychiatric abnormality," or a "deficiency of folate which causes a hematologic abnormality." LabCorp interprets the specification to clearly define a "deficiency of cobalamin" as the presence of a clinical or hematologic syndrome or both that responds to cyano-cobalamin treatment, and to acknowledge that some clinical or hematologic syndrome or neuropsychiatric abnormality must be present. Thus, LabCorp contends that the correlation step of claim 13 should be construed to require a showing of a separate hematologic or neuropsychiatric symptom to confirm the "correlation."

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The claim states that the method must correlate "an elevated level of total homocysteine ... with a deficiency of cobalamin or folate." This language does not require a further association between the level of total homocysteine and either a hematologic or neuropsychiatric abnormality or both. The claim only requires association of homocysteine levels with vitamin deficiencies. It requires no further correlation to confirm the relationship to vitamin deficiencies. The claim simply says nothing about a confirmatory step or a further correlation beyond the stated relationship.

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The preamble further supports the district court's reading of the claim: "A method for detecting a deficiency of cobalamin or folate in warm-blooded animals." This language restates that the invention detects vitamin deficiency. This introductory language does not relate those deficiencies to any particular abnormality. A preamble may provide context for claim construction, particularly, where as here, that preamble's statement of intended use forms the basis for distinguishing the prior art in the patent's prosecution history. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed.Cir.2002) (in rare circumstances, a preamble's recitation of intended use may serve to distinguish the prior art).

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An examination of the prosecution history of this patent brings the meaning of the preamble into focus. As originally filed, claim 13 did not contain the "correlating" step. The examiner rejected claim 13 under 35 U.S.C. § 112 because it did not "recite discrete, sequential process steps, for example, obtaining a sample, contacting the sample with, etc. The final step should be clearly related to the preamble of the claim." Rather than add a second step as the examiner suggested, however, the applicant responded: "[A]s applicants are the first to detect cobalamin or folate deficiency by assaying body fluids for total homocysteine, it is believed that they are entitled to a claim of equivalent scope, not limited to any particular steps or methods." After this response, the examiner dropped the § 112 objection, but rejected claim 13 under § 102: "In the absence of a correlation step, the preamble of claim 13 merely recites an intended use of the invention. The claim lacks a positive limitation for correlating to a particular condition and has only one method step recited." At that point, the applicant added the recommended "correlating" step. The examiner then allowed claim 13.

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This prosecution history ties the preamble directly to the "correlating" step. Specifically, the recitation of the intended use in the preamble makes this invention a method for detecting a vitamin deficiency. "Detecting" in the medical context requires evaluation of all test results, both positive and negative, to evaluate a patient's condition. For example, the results of a pregnancy test can either be positive or negative. Either result is informative to the patient. Similarly, in this case, the assaying step can identify an elevated or an unelevated level of total homocysteine. Then the "correlating" step can identify, in cases of elevated levels, a relationship or not to vitamin deficiency. The results in either the assaying or correlating steps are informative. Thus, the preamble supports the district court's construction that "correlating" includes ascertaining either a mutual or reciprocal relationship between total homocysteine and a vitamin deficiency. The preamble does not require this invention to show a further association with an abnormality.

The specification confirms that the claim language does not require as part of the method a confirmation that the elevated level causes some deleterious symptoms or abnormalities. LabCorp points to portions of the specification that discuss the relationship between the elevated levels and either clinical or hematologic symptoms. *See, e.g.*, '658 patent, col. 10, ll. 56-61; col. 12, ll. 8-15. LabCorp would expand those references to require some confirmatory step in the claim. The specification, however, does not require such a confirmatory step. Rather, the specification at one juncture acknowledges that the method can show vitamin deficiency without any clinical symptoms: "These findings led us to conclude that large numbers of patients with cobalamin deficiency lack the `typical' clinical and hematologic features usually expected to be present in cobalamin deficiency...." *Id.* at col. 11, ll. 40-45. In other words, the specification shows that the method can show an association between elevated levels and vitamin deficiency without any further clinical symptoms. Thus, the district court properly refused to import into the claims LabCorp's proposed limitation from the specification. The specification itself does not support such a limitation on the meaning of the claims.

As noted earlier, the district court construed "correlating" to mean a "mutual or reciprocal relationship between" the elevated levels and the vitamin deficiencies. The inventors discovered that assaying total homocysteine correlated with (or predicted relatively accurately) whether a patient had a deficiency of cobalamin or folate. *Id.* at col. 4, ll. 17-23; col. 10, ll. 35-42. The specification explains that an elevated level of total homocysteine often indicates a deficiency, while a non-elevated level indicates no deficiency. For example, the overview of the invention notes: "This invention pertains to ... methods for determining whether said warm-blooded animal has a cobalamin deficiency, a folic acid deficiency, *neither*, or both." *Id.* at col. 1, ll. 13-15 (emphasis added). Next, in the summary of the invention, the patentee stated: "Accordingly, assays for homocysteine can be used to determine the *presence or absence* of cobalamin and/or folic acid deficiency in warm-blooded animals." *Id.* at col. 5, l. 66-col. 6, l. 1 (emphasis added). This court observes that the perfect symmetry between "mutual or reciprocal" and "presence or absence" shows that the district court correctly placed the term "correlating" in its proper context with its proper meaning.

Finally, the patentee explained:

Once folate and/or cobalamin deficiency has been determined, the progress of treatment can be monitored by repeating the assays periodically during and after treatment. A drop in the level of homocysteine in the serum and/or urine after oral or parenteral administration of cobalamin and/or folate as the case may be confirms the diagnosis.

Id. at col. 10, ll. 18-24. This recitation confirms that the patentee anticipated assays without an elevated level of total homocysteine, i.e., the reciprocal relationship, would further confirm the diagnosis by showing an improvement trend after a physician prescribed treatment.

Taken in the context of the entire specification, "correlating" means relating total homocysteine levels to cobalamin or folate deficiency, a deficiency in both, or a deficiency in neither. In essence, "correlating" means to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both (i.e., a mutual relationship), and also to relate the absence of an elevated total homocysteine level to a deficiency in neither (i.e., a reciprocal relationship). The claim, in other words, provides that if the assay discloses "an elevated level of total homocysteine," the physician determines whether there is a cobalamin or folate deficiency by "correlating," i.e., comparing the elevated level with the normal homocysteine level. In sum, the specification and prosecution history confirm that the claim language "correlating," in the understanding of one of ordinary skill in this art field at the time of invention, includes both a mutual relationship between the presence of an elevated level of homocysteine and a vitamin deficiency and a reciprocal relationship between the absence of an elevated level of homocysteine and no vitamin deficiency. Further, the claim language does not require a confirmatory step linking these conditions to diagnosed or apparent symptoms. The district court correctly construed the claim.

LabCorp also raises claim construction arguments in its challenge to the trial court's assessment of damages. Specifically, LabCorp contends that only twenty percent of the assays have elevated levels of homocysteine and therefore only this percentage could form the basis for a damages award. As noted earlier, LabCorp itself urged the district court to define "correlating" to include either a mutual or a reciprocal relationship. In the damages calculation, however, LabCorp prefers to restrict the claim to correlations that yield mutual relationships while excluding any reciprocal relationships. This court declines the invitation to apply a different claim construction for computation of damages than for infringement liability.

As explained above, the mutual relationship is established when an elevated homocysteine level is present, whereas a reciprocal relationship is established when an elevated homocysteine level is absent. LabCorp's new damages argument, in essence, attempts to change its claim construction position to read out the reciprocal relationship that it initially urged. This court, as it does now, has previously declined such invitations. *Interactive Gift Express*, 256 F.3d at 1346 (Fed.Cir.2001) ("[A] party will be judicially estopped from asserting a position on appeal that is inconsistent with a position it advocated at trial and persuaded the trial court to adopt."). For all purposes in this litigation, this court affirms the district court's construction of the "correlating" step.

Direct Infringement

The jury found LabCorp liable for indirect infringement. The record must show the presence of direct infringement, however, to support the verdict of indirect infringement. *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed.Cir.1993) ("Liability for either active inducement of infringement or for contributory infringement is dependent upon the existence of direct infringement."). Thus, this court must examine whether there is substantial evidence in the record of the physicians' direct infringement. In that respect, the parties hinge the direct

infringement issue solely on whether the physicians perform the correlating step.¹ Hence, we review the record for substantial evidence of that step.

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Substantial evidence supports the jury's verdict. The record shows that physicians order assays and correlate the results of those assays, thereby directly infringing. LabCorp's Discipline Director, Dr. Peter Wentz, testified that the physicians receiving total homocysteine assays from LabCorp carry out the correlating step.² Specifically, Dr. Wentz testified that "the correlating step ... [is] a separate, distinct step that's performed by the physician who receives ... our results." Inventor Dr. Sally Stabler also testified that it would be malpractice for a doctor to receive a total homocysteine assay without determining cobalamin/folate deficiency.

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To support the verdict, the record does not need to contain direct evidence that every physician performed the "correlating" step. "It is hornbook law that direct evidence of a fact is not necessary. Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence." *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272 (Fed.Cir.1986) (citing *Michalic v. Cleveland Tankers, Inc.*, 364 U.S. 325, 330, 81 S.Ct. 6, 5 L.Ed.2d 20 (1960)). As discussed above, the record contains sufficient circumstantial evidence to permit the jury to imply that physicians directly infringe.

Active Inducement

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Section 271(b) of title 35 provides: "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b) (2000). Although not express in the statute, this section requires proof of intent to induce infringement. *See, e.g., Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed.Cir.1990) ("proof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement"). A patentee may prove such intent through circumstantial evidence, much like direct infringement as discussed above. *See Water Techs. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed.Cir.1988) (noting that "circumstantial evidence may suffice" in proving intent).

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The record contains such evidence of intent. LabCorp's own publications supply much of this evidence. LabCorp publishes both Continuing Medical Education articles as well as a Directory of Services that are specifically targeted to the medical doctors ordering the LabCorp assays. These publications state that elevated total homocysteine correlates to cobalamin/folate deficiency and that this deficiency can be treated with vitamin supplements. LabCorp's articles thus promote total homocysteine assays for detecting cobalamin/folate deficiency.

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Faced with these statements, LabCorp attempts to explain that these articles focus on heart disease rather than vitamin deficiency. As noted earlier, the patent does not require a correlation to some particular medical condition, but to a vitamin deficiency. The publications advocate use of the assay to identify a need for cobalamin/folate supplements. Thus, the vitamin deficiency remains the focus of the assay and the treatment (i.e., vitamin supplements).

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Accordingly, a reasonable jury could find intent to induce infringement because LabCorp's articles state that elevated total homocysteine correlates to cobalamin/folate deficiency. Moreover, the publications recommend treatment of this deficiency with vitamin supplements. Because "[i]ntent is a factual determination particularly within the province of the trier of fact," *Allen Organ Co. v. Kimball Int'l, Inc.*, 839 F.2d 1556, 1557 (Fed.Cir.1988), this court sees no reason to disturb the jury's finding regarding LabCorp's intent. Therefore, this court affirms the finding of indirect infringement based on the inducement analysis. This court declines to consider contributory infringement.

Invalidity

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A patent issued from the United States Patent and Trademark Office (PTO) bears the presumption of validity under 35 U.S.C. § 282. An accused infringer, therefore, must prove patent invalidity under the clear and convincing evidentiary standard. *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272 (Fed.Cir.2000). LabCorp argues that claim 13 is invalid on grounds of indefiniteness, lack of written description and enablement, anticipation, and obviousness. Likewise, LabCorp contends that claim 18, directed to the panel test, is also invalid on grounds of indefiniteness, and lack of written description and enablement.

Claim 13

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First, LabCorp contends that the "correlating" step in claim 13 is indefinite. 35 U.S.C. § 112, second paragraph, provides: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2 (2000). The requirement to "distinctly" claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles. *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed.Cir.2001); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1547 (Fed.Cir.1984). Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite. *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed.Cir.2001). In this case, as already noted, the claim construction exercise at the trial court produced a discernible and clear meaning. No "material ambiguities" cloud the meaning of "correlating" to the extent that one of skill in the art would find the claim wholly indefinite. *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 780 (Fed.Cir.2002) ("Only after a thorough attempt to understand the meaning of a claim has failed to resolve material ambiguities can one conclude that the claim is invalid for indefiniteness."). This court affirms the trial court's denial of JMOL on this ground.

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LabCorp next argues that the specification does not adequately describe the claimed invention under 35 U.S.C. § 112, first paragraph:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same....

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35 U.S.C. § 112, ¶ 1. This language contains both the written description and enablement tests for sufficiency of the specification's disclosure.

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With regard to the written description test, this court has previously explained, "the test for compliance with § 112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing." *Moba*, 325 F.3d at 1320 (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed.Cir.1991)). As in the claim construction section above, this court assesses the written description possession test "from the viewpoint of one of skill in the art." *Moba*, 325 F.3d at 1321. The record is replete with evidentiary support that physicians in homocysteine research, i.e., persons of ordinary skill in the art, understood from the specification that the '658 patent inventors possessed the "correlating" step at the time they filed the patent application. For example, the examiner suggested the word "correlating" to the '658 patentee, showing that the PTO read the specification to include that feature. Additionally, the record reflects that LabCorp's own expert and employees understood the meaning of "correlating." Accordingly, this court finds that substantial evidence supports the jury finding that claim 13 was adequately supported by the '658 patent's written description.

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The specification also shows that the patentee enabled the claimed invention. In *Union Pacific*, this court held that a claim was not enabled because it did not disclose use of a "comparing" step. 236 F.3d at 691. However, in *Union Pacific*, the inventors "purposely excluded computer programming details" necessary to perform the "comparing" step. *Id.* at 690. In this case, the correlating step does not require computer technology or extensive computations. Instead, the record shows repeatedly that the correlating step is well within the knowledge of one of skill in this art. The correlating step is a simple conclusion that a cobalamin/folate deficiency exists *vel non* based on the assaying step. The patentee did not conceal or fail to disclose this correlation, but instead featured it as the centerpiece of the invention. *See, e.g.*, '658 patent, col. 4, ll. 17-20 ("It has now been discovered that an elevated level of total homocysteine in tissues of warmblooded [sic] animals correlates both with cobalamin deficiency and with folic acid deficiency...."); *id.* at col. 5, ll. 64-66 ("It has been discovered that elevated levels of homocysteine in body tissue correlate with decreased levels of cobalamin and/or folic acid in said body tissue."); *id.* at col. 9, ll. 26-29 ("Homocysteine levels above these [previously specified] ranges are indicative of cobalamin and/or folate deficiency; the higher the level, the stronger the indication.").

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The prior art reference (Refsum) does not anticipate claim 13 under 35 U.S.C. § 102. "A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim." *EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 (Fed.Cir.2001) (citation omitted). At the outset, the Refsum article does not recite all of the claim 13 limitations. Thus, anticipation would have to rely on an inherent disclosure of undisclosed features, in this case, the "correlating" limitation.

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To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

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Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed.Cir.1991).

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Refsum does disclose that total homocysteine should be used to investigate "perturbations of homocysteine metabolism in humans during disease or pharmacological interventions that affect metabolism of one-carbon compounds." Refsum, however, does not specifically mention cobalamin or folate deficiencies. Indeed, one of the '658 patent inventors, Dr. Stabler, testified that cobalamin and folate deficiencies constitute just such a perturbation that Refsum suggested warranted further investigation. Rather than necessarily containing the correlation between homocysteine and cobalamin or folate deficiencies, Refsum simply invites further experimentation to find such associations. An invitation to investigate is not an inherent disclosure. Construed most favorably for LabCorp, Refsum discloses no more than a broad genus of potential applications of its discoveries. A prior art reference that discloses a genus still does not inherently disclose all species within that broad category. *See Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1262 (Fed.Cir.1989) ("Under [defendant's] theory, a claim to a genus would inherently disclose all species. We find [this] argument wholly meritless....").

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Moreover, the PTO considered Refsum in allowing the claims. The ' 658 patent itself discusses Refsum at length at column 6, lines 26-43 and the patent's second page cites Refsum as a reference. Where, as here, the PTO previously considered the prior art reference, LabCorp bears an even heavier burden to prove invalidity. *Hewlett-Packard*, 909 F.2d at 1467. ("This burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application." (citation omitted)). Accordingly, substantial evidence supports the jury's finding that Refsum does not anticipate claim 13 by inherency.

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The test of obviousness in 35 U.S.C. § 103 is the primary condition of patentability. Obviousness hinges on four factual findings: "(1) the scope and content of the prior art; (2) the differences between the prior art and the claims; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness." *Nat'l Steel Car, Ltd., v. Can. Pac. Ry., Ltd.*, 357 F.3d 1319, 1334 (Fed.Cir.2004). LabCorp posits that claim 13 is obvious in view of the Refsum article when combined with other references disclosing that partial homocysteine assays could help diagnose cobalamin or folate deficiency. First, as noted above in the anticipation analysis, the examiner considered the Refsum article and also considered all but one of the secondary references that LabCorp contends render the invention obvious in combination with Refsum. The one reference that the examiner did not consider is cumulative of the others. Thus, the heavy burden of proof in the anticipation case also applies to obviousness. *Hewlett-Packard*, 909 F.2d at 1467. Next, the secondary references do not refer to total homocysteine, but rather

to homocystine, one of the four components of total homocysteine. Thus, these secondary references do not add considerably to the Refsum disclosure. Finally, even if the secondary references disclosed total homocysteine, the record does not contain evidence showing that one of skill in the art would have been motivated to combine the various references. *Ecolchem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1372 (Fed.Cir.2000) ("Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577 (Fed.Cir.1984))). These points alone would suffice to support the jury verdict.

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Beyond these points, however, the record contains evidence of objective indicia that support the jury's nonobviousness verdict. The record, for example, shows that skilled artisans were initially skeptical about the invention. *See Hughes Tool Co. v. Dresser Indus., Inc.*, 816 F.2d 1549, 1556 (Fed.Cir.1987) (initial skepticism of experts is relevant to nonobviousness). The record also shows that Metabolite has licensed the invention to eight companies. *In re Sernaker*, 702 F.2d 989, 996 (Fed.Cir.1983) (extensive licensing supports nonobviousness). Substantial evidence, therefore, supports the implied jury factual findings that support its legal conclusion that claim 13 is not obvious in light of the Refsum article and the cited secondary references.

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In sum, this court rejects LabCorp's various attempts to invalidate claim 13. Accordingly, this court affirms the district court's denial of LabCorp's JMOL.

Claim 18

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Unlike claim 13, which Metabolite specifically asserted in its motion for partial summary judgment, Metabolite also requested the district court to declare that claim 18 covers the panel test method. Specifically, Metabolite sought a declaration that LabCorp's panel test that determines which particular vitamin is deficient infringes claim 18. The district court granted Metabolite's motion for partial summary judgment, finding that "[c]laim 18 covers LabCorp's performance of the panel test." In turn, LabCorp challenged the validity of claim 18 at trial. Neither party disputes that LabCorp continues to pay royalties for the panel test that provides the capability to identify which of the two vitamins is deficient.

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Before this court can reach the merits of LabCorp's validity challenge, however, it must first ascertain whether it has jurisdiction to consider this challenge. Subject matter jurisdiction is an inquiry that this court must raise *sua sponte*, even where, as here, neither party has raised this issue. *Textile Prods., Inc., v. Mead Corp.*, 134 F.3d 1481, 1485 (Fed.Cir.1998) ("Every federal appellate court has a special obligation to 'satisfy itself not only of its own jurisdiction, but also that of the lower courts in a cause under review,' even though the parties are prepared to concede it." (quotation omitted)); *see also Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1379 (Fed.Cir.2004) ("Any party or this court *sua sponte* may raise the question of subject matter jurisdiction.").

Although not as common as the scenario in which the alleged infringer seeks declaratory judgment against the patentee, it is possible for a patentee to also seek a declaratory judgment against a future infringer. See *Lang v. Pac. Marine & Supply Co., Ltd.*, 895 F.2d 761, 763 (Fed.Cir.1990) (noting that patentees seeking declaratory judgments against future infringers are rare, yet permissible). In order to demonstrate that an actual case or controversy exists, however, a patentee must demonstrate two elements. First, the patentee must show that the future infringer is "engaged in an activity directed to making, selling, or using subject to an infringement charge under 35 U.S.C. § 271(a)." *Lang*, 895 F.2d at 764. The patentee must then demonstrate that the defendant's acts represent a refusal to alter its course of action in light of the patentee's warning actions. *Id.*

The facts of this case, however, demonstrate that there is no real case or controversy regarding the LabCorp panel test, alleged to infringe claim 18. Neither party disputes that the license is still in effect as to the panel tests that LabCorp performs. This license is, in essence, a licensor's covenant not to sue the licensee. *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1346 (Fed.Cir.2001) (citation omitted). In turn, this court has held that a covenant not to sue deprives a court of declaratory judgment jurisdiction. *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed.Cir.1999) (citing *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1060 (Fed.Cir.1995)). Accordingly, a licensor who has implicitly covenanted not to sue a licensee by virtue of the license agreement itself cannot seek a declaratory judgment of infringement. Moreover, in light of LabCorp's continuing royalty payments on the panel test, LabCorp cannot itself challenge the validity of a claim for which it continues to pay royalties. *Cf. Gen-Probe Inc.*, 359 F.3d at 1382 (holding that a licensee who continued paying royalties to the licensor did not have sufficient apprehension of suit giving rise to declaratory judgment subject matter jurisdiction). The district court's opinion concerning the panel test's infringement of claim 18 was merely advisory. Accordingly, the district court lacked subject matter jurisdiction, and this court vacates that portion of the district court's judgment.

Breach of contract

The interpretation of a contract is a matter of state law. *Power Lift, Inc. v. Weatherford Nipple-Up Sys., Inc.*, 871 F.2d 1082, 1085 (Fed.Cir.1989). A license agreement is at its core a contract. In this case, both parties agree that New Jersey law governs their rights and obligations under the license, including the termination clause. Under New Jersey law, breach of contract is a question of fact properly reserved for a jury. *Magnet Res., Inc. v. Summit MRI, Inc.*, 318 N.J.Super. 275, 723 A.2d 976, 982 (App.1998). Thus, the standard of review for this court is whether substantial evidence supports the jury's finding.

The jury found that "LabCorp breached the license agreement by terminating it" for the Abbott test. LabCorp contends that it did not formally terminate the contract, because the contract requires that the licensee provide written notice. The record contains no evidence of a written termination. The record does show, however, that LabCorp stopped paying royalties on the total homocysteine tests. Refusal to pay royalties is a material breach of the license. See *Dow Chem. Co. v. United States*, 226 F.3d 1334, 1346 (Fed.Cir.2000). A material breach, in turn,

constitutes termination even where the license agreement termination clause does not expressly so provide. *See Apex Pool Equip. Corp. v. Lee*, 419 F.2d 556, 562 (2d Cir.1969) (holding that a licensee's material breach implicitly gives rise to a licensor's right to terminate); *see also Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 217 F.3d 8, 10 (1st Cir.2000) ("Every contract involves a bargained-for exchange of obligations, the material breach of which by one party gives the other party a right to terminate."); Restatement (Second) of Contracts § 237 (1981). This court, therefore, affirms the jury's finding that LabCorp breached the license agreement.

Enhanced damages

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LabCorp does not directly challenge the jury's willfulness finding. Instead, LabCorp contends that the district court did not discuss the *Read* factors for enhanced damages. *See Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826-27 (Fed.Cir.1992), *abrogated in part on other grounds, Markman*, 52 F.3d at 975. This court, therefore, addresses only the district court's grant of enhanced damages.

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To be sure, this court has enunciated its strong preference that a district court set forth its rationale for an award of enhanced damages to facilitate appellate review. *Read*, 970 F.2d at 828 ("To enable appellate review, a district court is obligated to explain the basis for the award, particularly where the maximum amount is imposed."). On the other hand, this court has also recognized the competing public policy of conserving judicial resources and has cautioned that a remand is a "step not taken lightly." *Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 814 (Fed.Cir.1990) (holding that a remand "should be limited to cases in which further action must be taken by the district court or in which the appellate court has no way open to it to affirm or reverse the district court's action under review"). As this court found in *Consolidated Aluminum*, "an appellate court need not close its eyes to the record where, as in this case, there is a way clearly open to affirm the district court's action." *Id.* at 814. Accordingly, this court considers the findings in the record for an abuse of discretion in doubling the infringement damages.

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First, this court considers the second *Read* factor, namely whether LabCorp conducted an investigation regarding the scope of the '658 patent in order to form a good-faith belief. *Read Corp.*, 970 F.2d at 827. LabCorp concedes that Dr. Wentz alone determined that the Abbott total homocysteine tests did not infringe the '658 patent and therefore LabCorp would not need to continue paying royalties to Metabolite. Dr. Wentz himself testified during trial that his determination that the '658 patent did not extend to the Abbott total homocysteine tests was based solely on his interpretation of the license agreement between LabCorp and Metabolite. Moreover, Dr. Wentz testified that he did not consult the '658 patent itself. He also conceded his lack of training in patent law. Based on this evidence alone, the district court could easily have determined that LabCorp did not conduct a reasonable investigation into potential infringement by the Abbott total homocysteine tests. *See Underwater Devices Inc. v. Morrison-Knudsen Co., Inc.*, 717 F.2d 1380, 1390 (Fed.Cir.1983) (affirming district court's grant of enhanced damages where defendant obtained incompetent opinion from in-house counsel who was not a patent attorney, did not consult the patent file histories, and prepared a memo containing "only bald, conclusory and unsupported remarks regarding validity and infringement of the [] patents").

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LabCorp's failure to conduct a reasonable and independent investigation regarding the Abbott total homocysteine test is further highlighted by the very terms of the license agreement between LabCorp and Abbott Labs. In the license agreement, Abbott Labs specifically excludes the '658 patent from a warranty covered by an indemnity provision. The warranty specifically excludes:

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[A]ny claim of infringement which may arise under the subject matter of U.S. Patent 4,940,658 and any U.S. or foreign patents claiming priority therefrom or otherwise related thereto. *Except with respect to the foregoing* and at the time of signing this Agreement, Abbott has no reasonable knowledge of any infringement of third party patent rights that would arise from the use of the Imx Homocysteine Research Assay.

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(emphasis added). By accepting this provision, LabCorp knew or should have known that Abbott Labs believed the use of the Abbott test might infringe the ' 658 patent. This language in the license agreement would have put a reasonable licensee on notice to conduct its own investigation regarding the ' 658 patent coverage of the Abbott total homocysteine test.

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In addition to the second *Read* factor, the record also reflects that LabCorp is a large company with extensive financial means, i.e., *Read* factor four. LabCorp's infringing activities of claim 13 began in 1998 without any attempts to remedy the infringement, *Read* factors six and seven, respectively. The district court therefore had evidence before it warranting consideration of at least four *Read* factors.

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That the district court did not explicitly set forth its rationale for awarding Metabolite enhanced damages based on LabCorp's willful indirect infringement is not fatal to its decision. As in *Consolidated Aluminum*, "[n]o useful purpose would be served by a remand to enable the district court to tell [this court] in express terms what [it] already know[s] from the record." 910 F.2d at 815. On the basis of the appellate record, this court can readily discern at least four *Read* factors that the district court likely considered when using its discretion to double the infringement damages. Accordingly, this court holds that the district court did not abuse its discretion in enhancing the infringement damages. The district court's failure to discuss the *Read* factors, although contrary to this court's strong preference for the enumerated bases underlying its decision, in this case was at most harmless error.

Injunction

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The district court granted Metabolite's motion "to enjoin LabCorp from performing `any homocysteine-only test, including without limitation homocysteine-only tests via the Abbott method.'"

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LabCorp argues that the injunction is too broad because it extends beyond the scope of the claims. To the contrary, the injunction simply addresses LabCorp's specific acts constituting indirect infringement. LabCorp performs the assays upon request from physicians and in doing so indirectly infringes. The district court correctly enjoined LabCorp from infringement. LabCorp also argues that the injunction is defective in form under the Federal Rules of Civil Procedure, because Rule 65(d) requires that a district court "set forth the reasons" for issuing an injunction. The district court's order states that it "finds no sound reason for denying the injunction." While this statement does not explicitly set forth detailed reasons, the district court properly granted the injunction because LabCorp was found to infringe. *See W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1281 (Fed.Cir.1988) ("[A]n injunction should issue once infringement has been established unless there is a sufficient reason for denying it."). The district court's brevity is not reversible error.

CONCLUSION

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The district court did not err in denying JMOL, awarding enhanced damages, and granting the permanent injunction.

COSTS

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Each party shall bear its own costs.

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AFFIRMED.

Notes:

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This court, therefore, does not address the assaying step

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Peter Wentz has a doctoral, not a medical, degree

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SCHALL, Circuit Judge, concurring-in-part, dissenting-in-part.

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I agree with the majority's conclusions with respect to validity, the absence of a case or controversy regarding infringement of claim 18, breach of contract, enhanced damages, and the district court's injunction. However, I respectfully dissent from the majority's construction of claim 13 of the ' 658 patent. Because I think claim 13 covers only the correlation of elevated levels of homocysteine, I would remand the case for a recalculation of the damages resulting from indirect infringement.

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Claim 13 of the '658 patent is an independent claim for a two-step method:

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13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:

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assaying a body fluid for an elevated level of total homocysteine; and

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correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

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Col. 41, ll. 58-65. Proper construction of the terms "correlating" and "elevated" is dispositive of the issue of infringement of claim 13. The district court construed "elevated" to mean "raised above the normal range," and "correlating" as "to establish a mutual or reciprocal relationship between." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, No. 99-Z-870, slip op. at 2-3 (D.Colo. Nov. 29, 2000) (*Markman Order*). Disagreeing with neither of these constructions, the majority holds that when a patient's homocysteine level is not "elevated," claim 13 may nevertheless be infringed because "correlating" includes establishing both a mutual relationship and a reciprocal relationship. The majority states:

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In essence, "correlating" means to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both (i.e., a mutual relationship), and also to relate the absence of an elevated total homocysteine level to a deficiency in neither (i.e., a reciprocal relationship)... [T]he specification and prosecution history confirm that the claim language "correlating," in the understanding of one of ordinary skill in this art field at the time of invention, includes both a mutual relationship between the presence of an elevated level of homocysteine and a vitamin deficiency and a reciprocal relationship between the absence of an elevated level of homocysteine and no vitamin deficiency.

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In my view, the majority impermissibly expands the scope of claim 13 beyond the actual words of the claim.

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I begin with what I see as the controlling principles of claim construction. When interpreting the claims of a patent, the court should look first to the intrinsic evidence of record: the claim, the specification, and, if in evidence, the prosecution history. *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). There exists within the intrinsic evidence a "hierarchy of analytical tools." *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed.Cir.1998). First, the language of the claim should be considered — "[t]he actual words of the claim are the

controlling focus." *Id.* The claim language defines the bounds of claim scope. *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 619-20 (Fed.Cir.1995). Because the claims define the patentee's right to exclude others, "the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed.Cir.1998).

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If the meaning of a claim term is clear on its face, consideration of the remaining intrinsic evidence is restricted to determining if a deviation from the clear language of the claim is specified. *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed.Cir.2001). The court may consider the patent specification in construing whether the patentee has intended for the meaning of a claim term to deviate from its ordinary meaning. *Vitronics*, 90 F.3d at 1582. The court may also consider the prosecution history, if it is in the record, for evidence of an intentional deviation from the plain meaning of a claim term. *Id.*

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Beginning with the ordinary meaning of the claim terms, I too do not disagree with the district court's construction of the terms "elevated" and "correlating." Nor do I disagree with the majority's conclusion that the claim language does not require a further association between the level of total homocysteine and either a hematologic or neuropsychiatric abnormality or both. I cannot agree with the majority, however, that claim 13 is infringed when the test demonstrates that a patient's homocysteine level is *not* "elevated." The plain language of the claim requires "elevated" levels of homocysteine, and a heavy presumption weighs in favor of the ordinary and customary meaning of that term. *CCS Fitness v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed.Cir.2002). As the district court properly construed the term, "elevated" requires a level of homocysteine that is "raised above the normal range." *Markman Order*, slip op. at 2-3. Thus, for claim 13 to be infringed, the homocysteine assay must evince a level of homocysteine that is raised above the normal range. In short, in my view the majority disregards the explicit limitation in claim 13 that only an "elevated" level of homocysteine can be "correlated" with a vitamin deficiency.

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There is no language in claim 13 addressing unelevated levels of homocysteine, nor language that unelevated levels of homocysteine are to be correlated with the absence of a vitamin deficiency. Ordinary meaning thus dictates that a patient's homocysteine level be "elevated" in order for a physician to practice claim 13. If the patient's homocysteine levels are not "elevated," by the plain language of the claim, there is no "correlating" to be done. The language of claim 13 does not suggest that the claim encompasses the correlation of unelevated levels with the absence of a deficiency, for the introductory phrase claims "a method for detecting a deficiency," without addressing at all the detection of the absence of a deficiency. '658 patent, col. 41, ll. 58-59.

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We have repeatedly stated that "[c]ourts can neither broaden nor narrow claims to give the patentee something different than what he has set forth." *Tex. Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1171 (Fed.Cir.1993) (quoting *Autogiro Co. v. United States*, 181 Ct.Cl. 55, 384 F.2d 391, 396 (1967)); *Oak Tech., Inc. v. Int'l Trade Comm'n*, 248 F.3d 1316, 1329 (Fed.Cir.2001). In this case, however, the majority has permitted claim 13 to be infringed even when homocysteine assays result in unelevated levels. The majority thereby broadens claim 13

to also include, although it is not expressly claimed, correlating unelevated levels of homocysteine with the absence of a vitamin deficiency.

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Relying on language from the specification and the prosecution history, the majority brings assays that demonstrate unelevated levels of homocysteine within the province of claim 13 by focusing its construction on the term "correlating." The problem I have with this approach is that it ignores the term "elevated." In addition, because the term "elevated" in claim 13 is unambiguous on its face, the specification and prosecution history of the ' 658 patent may be consulted only to determine if the patentee intended to deviate from ordinary meaning. *Interactive Gift Express*, 256 F.3d at 1331. There is no evidence before us that any deviation was intended. Throughout the specification, the term "elevated" is consistently used to refer to levels that are raised above average. For example, the specification explains that

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The normal range for homocysteine in human serum is from about 7 to about 22 μmol/liter. *Homocysteine levels above these ranges* are indicative of cobalamin and/or folate deficiency....

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When homocysteine levels are *elevated* in individuals without inherited defects, at least one of folate or cobalamin is deficient.

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'658 patent, col. 9, ll. 23-29, 38-40 (emphases added). Nor is there any evidence from the prosecution history that the patentee relinquished this claim construction in an amendment or in an argument to overcome or distinguish a prior art reference. *Vitronics*, 90 F.3d at 1582. Accordingly, I construe Claim 13 to require an assay that demonstrates an "elevated" homocysteine level, or one "raised above the normal range," in order for the claim to be practiced.

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Pursuant to this claim construction, claim 13 is only infringed when the assays performed by LabCorp reveal elevated levels of homocysteine. As LabCorp explains, and as Metabolite does not dispute, approximately eighty to eighty-four percent of the assays LabCorp processes reveal unelevated levels of homocysteine. I would therefore vacate the jury's verdict that the assays resulting in unelevated levels of homocysteine infringed claim 13, and further vacate and remand the jury's verdict on damages for recalculation based only on those infringing assays that demonstrate elevated levels of homocysteine.