

United States Court of Appeals for the Federal Circuit

99-1578, 00-1093, -1094

BIOTEC BIOLOGISCHE NATURVERPACKUNGEN GmbH & CO. KG,

Plaintiff-Cross Appellant,

v.

BIOCORP, INC. and NOVAMONT, S.p.A.,

Defendants-Appellants.

Larry R. Laycock, Workman, Nydegger & Seeley, of Salt Lake City, Utah, argued for plaintiff-cross appellant. With him on the brief were David R. Wright and David R. Todd.

Chester T. Kamin, Jenner & Block, of Chicago, Illinois, argued for defendants-appellants. With him on the brief were F. Scott Kieff and Katherine J. Strandburg of Chicago, Illinois, and Paul M. Smith and Marc A. Goldman, of Washington, DC.

Appealed from: U.S. District Court for the Central District of California

Judge Edward Rafeedie

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DECIDED: May 14, 2001

Before MAYER, Chief Judge, NEWMAN and SCHALL, Circuit Judges.

NEWMAN, Circuit Judge.

Biocorp, Inc. and Novamont S.p.A. (together "defendants") appeal the judgment of the United States District Court for the Central District of California,¹ entered upon a jury verdict that certain biodegradable starch-based products infringe United States Patents Nos. 5,362,777 (the '777 patent) and 5,280,055 (the '055 patent). The patents are owned by Biotec

1 Biotec Biologische Naturverpackungen GmbH & Co.v. Biocorp, Inc., CV 98-

Biologische Naturverpackungen GmbH, and cover certain inventions of Dr. Ivan Tomka relating to a product called "thermoplastically processable starch" (TPS). According to these inventions starch such as that of wheat, potatoes, or corn is modified to produce TPS, a biodegradable polymeric material that can be shaped into plastic-type articles by standard thermoplastic processing techniques, typically injection molding or extrusion. The patented product is described as an important improvement on prior starch-based plastics, a witness calling the Tomka TPS "a landmark in starch polymer material."

Biotec charged the defendants with infringement and inducing infringement of the '777 and '005 patents, based on Novamont's production in Italy of starch-based polymeric products and their importation and sale by the defendants in the United States. The defendants responded that the Biotec patents are not infringed, are invalid, and are unenforceable. On motions for summary judgment the district court decided the issues of validity and enforceability in Biotec's favor. The issues of infringement were tried to a jury, which found the defendants liable for infringement or inducement of infringement, but not willful infringement. The jury awarded compensatory damages, assessing \$750,000 against Novamont and \$250,000 against Biocorp. The district court entered the judgment, enjoined further infringement, and denied the duly made post-trial motions. This appeal followed. Biotec cross-appeals the judgment that the infringement was not willful.

THE INVENTIONS

It was known to make plastic-forming starch, called "destructured starch," by swelling and kneading native starch at elevated temperatures to produce a thermomechanically

transformed starch. This procedure was conducted in the presence of added water, for native starch, which contains 10-20% water, chars at the high temperatures needed to transform the starch. However, the resultant high water content is disadvantageous for further processing using standard plastic-forming equipment and temperature conditions, for the water foams as steam and leaves undesirable bubbles in the final plastic product.

To solve this problem, the thermoplastically processable starch of the '777 patent is produced by preparing destructure starch without added water, instead conducting the destructure transformation in the presence of a plasticizer or other additive, thereby lowering the melting point of the composition. According to the '777 patent the starch/additive composition is melted at a temperature below the decomposition temperature of the starch, and mixed until the product is substantially free of water and the crystalline content is reduced to below 5%. Crystalline content is a measure of the mechanical transformation of the starch, and the removal of water from the product eliminates the disadvantageous foaming and bubbling during further plastic processing.

Claims 1 and 20 are representative of the claims in suit of the '777 patent, with emphases added to terms that were construed in connection with the charges of infringement:

1. A method of preparing thermoplastically processable starch which is a substantially water free combination of starch with at least one additive, the method comprising admixing starch with at least 5 weight percent based on the weight of the mixture of at least one additive, said additive being such that it reduces the melting point of the starch in the mixture to below the decomposition temperature of the starch, said additive having a solubility parameter of more than $15 \text{ cal}^2 \text{ cm}^{-2/3}$, said additive having a vapor pressure of less than 1 bar in said mixture at a temperature of about the melting point of said mixture, and melting and mixing said admixture until it is substantially water free and until the crystalline content is less than 5%.

20. A thermoplastically processable starch comprising a substantially water free, homogeneous mixture having a crystalline content of less than 5% of starch and at least 5 weight % of at least one additive having a solubility parameter of

more than $15 \text{ cal}^2 \text{ cm}^{-2/3}$, said additive having a vapor pressure in the mixture of less than +1 bar at about the melting point of the homogeneous mixture, and the melting point of the mixture being lower than the decomposition temperature of the starch.

The '055 patent is directed to an interactive blend of the thermoplastically processable starch of the '777 patent, a cellulose derivative, and a phasing agent. The product of the '055 patent is described as having advantageous resistance to moisture and to be more readily processed in standard plastic molding machinery. Claim 1 is the broadest claim:

1. Biodegradable mould material or polymer blend with a high resistance to moisture, containing at least thermoplastically processable starch and a cellulose derivative and 5-25% by volume of a phasing agent, which by physical interaction or chemical reaction or both with the cellulose derivative phase and the phase of the thermoplastically processable starch makes it possible to improve the adhesion of both phases.

Neither side argues the '055 patent separately. Thus its fate accompanies that of the '777 patent.

The evidence and argument relating to the meaning and scope of the claims were presented at trial, in the presence of the jury. The district court construed the disputed claim terms in the court's instructions to the jury. The defendants argue that the district court incorrectly construed the terms "substantially water free," "thermoplastically processable starch," and "crystalline content." They state that on the correct construction of these terms no reasonable jury could have found infringement of these patents. The district court, however, sustained the verdict.

"Substantially Water Free"

The district court instructed the jury that "substantially water free" means that "the resulting mixture has a total water content of less than 5%, as measured by dividing the weight

of the water in the resulting mixture by the weight of the starch, water, and additives." The defendants argue that the prosecution history requires not simply less than 5% water content, but substantially less than 5%, pointing to various statements in the prosecution history discussing a water content of 1% or 3%. The defendants state that a 3% limit would exclude all or most of the Novamont production.

The term "substantially water free" is not given a numerical limit in the specification of the '777 patent. The term was explained during prosecution as distinguishing the water content of the '777 product from that produced in the cited reference to Lay. Lay describes producing destructured starch in the presence of additives such as glycerine and sorbitol (also used in the '777 patent), wherein the starch used as starting material has "a water content of 5 to 30% [by weight] based on the starch/water component."

The examiner of the '777 patent had initially objected to the usage in the claims of "substantially water free," stating that "nothing appears on the record which is clearly indicative as to what may be embraced by the term 'water free.'" In response Dr. Tomka filed two declarations, one by Jean Pierre Mercier, a professor of polymer science at Louvain University, and the other by Ulrich W. Suter, a professor of macromolecular chemistry at ETH-Zurich Institut für Polymere. Both declarants were described as experts in the field of starch chemistry. Both stated that "those skilled in the art would not consider starch containing 5% water as being 'substantially water free,'" and that "it is necessary for the water content to be less than 5% before starch can be considered 'substantially water-free.'"

The defendants argue that the declarants worked with water contents of 1% or 3%, not 5%, and that they stated that water content above 3% resulted in brittleness on aging. Biotec responds that the 1% referred to in the declarations related to water content for processing of

the TPS by any conventional processing methods, and the 3% related to processing by certain injection molding units. Biotec states that these figures do not affect the support in the declarations and elsewhere in the prosecution history for the construction that "substantially water free" means, simply, less than the 5% water in the Lay reference. Biotec states that the patent examiner accepted that "substantially water free" means less than 5% water, in accepting that this term distinguished the '777 invention from the Lay reference. Biotec also points to claim 24 (not in suit) which is specific to a "moisture content less than 1.0%," and invokes the doctrine of claim differentiation to support the broader scope of "substantially water free."

The meaning of "substantially water free" was the subject of testimony during trial, where Dr. Tomka and Biotec's expert Dr. Meijer explained the declarations and other parts of the prosecution history. The district court's ruling and jury instruction that "substantially water free" means a water content below 5% is in accordance with the prosecution history and was supported by the evidence. That claim construction is confirmed.

Computation of Water Content

Claim 1 recites a "substantially water free combination of starch with at least one additive," and claim 20 recites "a substantially water free, homogeneous mixture." The parties disagree on the method of computing the water content. The district court instructed the jury that the calculation is based on the water content of the total mixture. According to the court's instructions, in calculating the percentage of water the weight of the total mixture of starch, water, and additives forms the denominator of the fraction, with the weight of the water alone as the numerator.

The defendants argue that only the weight of starch plus water (omitting the additives) should form the denominator, since that is the method of computation in the Lay reference that was distinguished by its water content of at least 5%. The defendants point out that claims should be construed to sustain their validity, and argue that the district court's construction renders the claims invalid in light of Lay because the '777 products would contain over 5% water if calculated as in Lay. The defendants also state that by the Lay equation the Novamont products are non-infringing because they would be calculated to contain over 5% water.

Biotec responds that Lay's method of calculation is similar to the method used in the '777 patent, for the additives will entrain water and thus the weight thereof is included in the denominator in both methods of calculation. Lay teaches that the "water insoluble" polymer additive can be expected to absorb up to 5% water, and the glycerine and sorbitol would absorb more than 5% water. Thus, Biotec states that at concentrations in the range of 5% the method used by the district court and the method the defendants advanced at trial would have produced similar results. The issue of how to conduct the calculation was fully aired at trial. The district court's claim construction is in accordance with the specification and supported by the evidence, and is affirmed.

Water Content of the Starting Material

The defendants also argue that the prosecution history of the '777 patent limits the claims to a process that uses only starch that is pre-dried to be substantially water free at the beginning of the process, and excludes starch that is initially melted with its natural water present. Native starch is described as containing about 10-20% water. The defendants point to an argument presented by Biotec during prosecution, that its process starts with substantially

water-free starch. Biotec describes the presentation of this argument as an "obvious error" by its agent.

Biotec explained at trial that in a parent application it had initially presented claims limited to a process in which pre-dried water-free starch was used as an alternative starting material, along with claims to the process that started with native starch. The specification states that either pre-dried or native starch may be used, and the claims as granted (except for claim 18, which calls for a water content of "about 17% before said mixing and melting") do not distinguish between these starting materials. Nonetheless, at one point in the prosecution Biotec indeed made the argument that the starting starch was water-free. Biotec characterizes this as an obvious error, pointing out that this was an isolated statement and manifestly contradicted by the rest of the prosecution history, including other statements in the same amendment; Biotec states that this is readily seen as attorney error. Biotec points out that dependent claim 18 is specific to starch having a water content of 17%, thus making clear that pre-dried starch is not the only starting material.

The defendants respond that it is not the court's role, or within its authority, to correct the patentee's error. They argue that a statement during prosecution that so clearly limited the claims should be construed against the patentee, whether or not the statement was made in error and whether or not the error would have been recognized as such by a reader of the prosecution history.

An error in the prosecution record must be viewed as are errors in documents in general; that is, would it have been apparent to the interested reader that an error was made, such that it would be unfair to enforce the error. The defendants do not argue that this statement led them to believe that it clearly limited the invention that was claimed. A person of reasonable

intelligence would not be misled into relying on the erroneous statement, for it is contrary not only to the plain language of the claims and the specification, but also to other statements in the same prosecution document. In Intervet America, Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1054, 12 USPQ2d 1474, 1477 (Fed. Cir. 1989) the court dealt with an erroneous statement during prosecution and held: "When it comes to the question of which should control, an erroneous remark by an attorney in the course of prosecution of an application or the claims of the patent as finally worded and issued by the Patent and Trademark Office as an official grant, we think the law allows for no choice. The claims themselves control." We sustain the district court's construction of the claims as not limited to the use of starch from which water was removed by pre-drying before processing.

Crystalline Content

The '777 claims require that the crystalline content in the thermoplastically processable starch is less than 5%. The district court construed this term as measuring "the amount of crystalline lattice structure associated with the native starch compared with the resulting mixture. A resulting mixture has a 'crystalline content of less than 5% of starch' if it has 5% or less of the crystalline content of native starch." The court so instructed the jury.

The dispute at trial centered on the measurement of the crystalline content, the defendants arguing that on correct measurement the Novamont product is excluded. The '777 patent used powder x-ray diffraction to measure crystalline content. However, the parties disagreed as to which peaks in the x-ray diffraction plots of the Novamont product should be counted as representing crystalline content. Biotec stated that some of the peaks shown in the diffraction plots for the Novamont product represent lipid-amylose complexes (referred to as V-

complexes) and do not represent "true crystallinity" of starch, and thus should not be counted in determining crystalline content.

The defendants' expert stated that the '777 patent teaches that all of the peaks on the diffraction plot are counted in measuring crystallinity. Biotec's expert stated that the '777 patent's diffraction plots were for potato starch, which does not contain V-complexes, and that this explains why all of the peaks were counted to measure starch crystallinity. Biotec stated that Novamont uses corn starch, whose V-complexes give rise to additional x-ray diffraction peaks that are not due to starch crystallinity and that should not be counted. Biotec's expert testified that those skilled in this art do not consider V-complexes to be "crystalline content" of starch. The defendants stressed that the '777 patent does not draw this distinction, and argued that the patent requires determining the overall crystallinity of the resultant product, whether the crystalline-measuring diffraction peaks are due to starch or to V-complexes.

There was evidence and argument on both sides of the question of whether all of the diffraction peaks in the Novamont product should be counted in deciding crystallinity. The district court resolved this aspect, as a matter of claim construction, by describing the crystalline structure as that "associated with the native starch." The defendants argue that the district court should have gone further, and decided which peaks in the diffraction plots of the Novamont products represent crystalline starch and which represent V-complexes. The defendants argue that the jury should have been specifically instructed which peaks of the accused products, if any, should be ignored in calculating their crystalline content, and that the jury was improperly permitted to decide whether the accused products had a crystalline content in the infringing range.

We conclude that the district court reasonably satisfied its obligations of claim

construction. The court was not required to remove the expert testimony from the hearing of the jury; the court's obligation was to assure that evidence was reliable and relevant to the issue of infringement. See Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Daubert, as elaborated by General Electric Co. v. Joiner, 522 U.S. 136 (1997) and Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999), requires that the court assure that the scientific or technologic evidence be relevant and of appropriate scientific validity, according to the standards of the discipline. When competing views of qualified experts satisfy these criteria, the trier of fact may consider them in reaching its decision. Indeed, it would contravene fundamental principles of due and fair process to withhold evidence of disparate scientific opinion relevant to the findings -- in this case of infringement vel non -- required of the jury.

"Melting"

The defendants state that the district court "failed to discharge its duty under Markman" when the court declined to construe 'melting.'" They state that the correct construction of "melting" would avoid infringement. Biotec states that the defendants did not object to the jury instruction on the ground that it did not construe "melting"; the defendants respond that indeed they objected, but the district court rejected their position. Despite this debate, the meaning of "melting" does not appear to have required "construction," or to depart from its ordinary meaning. The issue in dispute was the application of the melting step in the accused process, a factual question of infringement.

INFRINGEMENT

The jury did not specify whether it found literal infringement or infringement under the doctrine of equivalents. Because we conclude that substantial evidence supports a finding of

literal infringement, it is not necessary for us to address the issue of infringement under the doctrine of equivalents.

On appeal the defendants place their strongest emphasis on the "substantially water free" limitation, arguing that errors of claim construction preclude sustaining the jury verdict as a matter of law. They point out that all of Biotec's evidence as to the water content of the accused products related to the water content when the product was produced by Novamont in Italy. They argue that the water content was measured at the wrong place in the processing sequence and by incorrect procedures. They also state that the Novamont products gain water to exceed the 5% limit after they are manufactured, either by quenching the hot pellets in water or from absorption of water from the ambient air while in storage or shipment, and thus are not "substantially water free" when reaching the United States. Thus they argue that the absorption of water at various times during or after the manufacturing process renders them non-infringing as manufactured or by the time they are imported, and that correctly construed claims could not be found to be infringed.

For the process claims, the defendants also argue that they do not infringe these claims because the increase in water content after processing into pellets constitutes a "substantial change" in terms of 35 U.S.C. §271(g). Thus the defendants argue that the United States patents are not infringed, whatever the water content in Italy when the product is first produced, because that product absorbs additional water by the time it reaches the United States.

The Product Claims

Infringement of product claims by an imported product requires that the product be viewed in the form in which it is present within the United States. See 35 U.S.C. §271(a)

("whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States" infringes the patent). However, evidence of foreign activities may be relevant to determination of infringement upon importation. Both sides presented evidence concerning Novamont's product and process.

As we have discussed, the jury was instructed that "the phrase 'substantially water free' means that the resulting mixture has a total water content of less than 5 percent." The defendants argue that the word "total" requires including all water, however and whenever it enters the "resulting mixture," including water absorbed by the product after it is produced.

The defendants argue that Biotec did not prove, with adequate evidence, that the product as manufactured in Italy contained less than 5% water, because Biotec's witness Dr. Meijer did not measure the water content of the Novamont product directly; instead, Dr. Meijer calculated the water content as the difference between the amount of water collected in the final out-gassing step of Novamont's manufacturing process, and the water content of the starting ingredients. In making this calculation Dr. Meijer relied on production data provided by Novamont. He testified that about 90% of the lots showed a water content of less than 5%, and that the average of all the lots was below 5%. The defendants argue that this evidence was inadequate because it did not measure water content directly, and that the water content adduced therefrom must be rejected. Biotec responds that it was obliged to use this procedure because Novamont would not permit it to take actual samples of the product during the manufacturing process.

A reasonable jury could have accepted Dr. Meijer's evidence as probative of the water content of the product as produced in Italy. He obtained the data from Novamont, and also presented Novamont documents showing that certain grade products had a water content of

0.8-1.0% by total weight, another grade 3.2-3.8% water content, and another grade 3.5-4.8%. Although the defendants argue that the water content of the Novamont product immediately after degassing is higher than 5%, and that "almost all pellets packed for shipment" had a water content above 5%, the defendants' briefs do not explain these differences, or negate the substantial evidence supporting the jury verdict.

There was evidence that the pellets were shipped in airtight containers to inhibit the absorption of water. Biotec presented evidence that any water absorbed by the pellets after production is of a different, loosely bound nature, and argued that such water is not part of the product that is described in the claims. There was evidence at trial that such absorbed water was readily lost when the imported pellets were melted preparatory to extrusion.

To the extent that there was conflicting evidence, the jury's evaluation of the evidence could include determinations of the reliability of the data and the credibility of the witnesses. See Al-Site Corp. v. VSI Intern., Inc., 174 F.3d 1308, 1317, 50 USPQ2d 1161, 1165 (Fed. Cir. 1999) ("As the finder of fact, the jury receives deference for its function of weighing witness demeanor, credibility, and meaning.") (citing Anderson v. City of Bessemer City, North Carolina, 470 U.S. 564, 575 (1985) (factfinder entitled to deference on credibility determinations)); Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1189, 48 USPQ2d 1001, 1008 (Fed. Cir. 1998) ("It is not the function of this court to reweigh the evidence presented to the jury.")

Biotec also argues that the jury's verdict is sustainable on the theory that the defendants induced infringement when they instructed customers to melt the resin pellets before using them, citing the evidence that this melting drives off any after-absorbed water. The defendants argue that this evidence can not support a verdict based on inducement of infringement,

because there was no direct evidence of direct infringement; that is, there was no evidence that the customers actually followed these instructions. The defendants argue that their instructions to melt the pellets can not be grounds of "induced" infringement unless it is also established that the user was thereby induced to and did engage in direct infringement. Biotec responds that it was not controverted that the pellets are melted before they are used in plastic-forming machines, and that a reasonable jury could have found that the customers followed the instructions to provide an initial "degassing" to remove entrained water. The defendants also argue that if melting or degassing is conducted in a closed system the water content would not be reduced. These arguments, insofar as they were presented to the jury, do not overcome the presence of substantial evidence in support of the jury verdict.

The verdict form did not distinguish between the theories of direct and induced infringement. There was substantial evidence to support a jury verdict either that the product as imported was an infringing product, or that the defendants induced infringement with its instructions for use of the imported product. The defendants have not met their burden of establishing that the jury's verdict can not stand.

The Process Claims

Biotec also charged infringement of its process claims pursuant to 35 U.S.C. §271(g), which prohibits the importation into the United States of articles made abroad by a process patented in the United States.² A purpose of §271(g) was to bring United States law into

2 35 U.S.C. ' 271(g):

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.... A product which is made by a patented process will,

conformity with that of other nations, with certain safeguards as set forth in the statute. See Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 1347, 56 USPQ2d 1332, 1339 (Fed. Cir. 2000). One of these safeguards is that there is not infringement if the imported product of the patented process is "materially changed by subsequent processes," 35 U.S.C. §271(g)(1).

The defendants argue that even if the patented process were practiced in Italy, the product of that process is "materially changed" because it absorbs water between its manufacture and arrival in the United States, increasing the water content above the 5% limit of the claims. They also argue that a product that no longer infringes the product claims must be deemed to be materially changed, as a matter of law. Thus the defendants argue that there was no question for the jury, and noninfringement under §271(g) should be held as a matter of law.

On the question of material change, there was testimony about the nature of the absorption of water by Novamont's thermoplastically processed starch, and its subsequent desorption on use in the United States. Reference was made at trial to the specification of the '777 patent, which described the "hydrophilic nature" of the product. Whether a change in a product is material is a factual determination, and is properly for the trier of fact. There was substantial evidence whereby a reasonable jury could have found that the product made by the infringing process was not materially changed by the absorption of water after manufacture.

The verdict of infringement must be affirmed.

for purposes of this title, not be considered to be so made after--(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product.

VALIDITY

The defendants argue that the district court erred in granting summary judgment that the '777 and '055 patents are not invalid. They point to several references asserted to render the patents invalid on grounds of either anticipation or obviousness. Biotec responds that several of the references now cited were not presented to the district court in connection with the summary judgment proceedings, and that other submissions were properly rejected by the district court.

During the summary judgment proceedings the defendants had requested a continuance pursuant to Rule 56(f)³ for the purpose of obtaining deposition evidence from the inventor. The district court granted the request, and ordered the defendants to file a supplemental brief describing the deposition and explaining "precisely why the deposition testimony would preclude summary judgment." The court thus granted permission to submit certain specified evidence out of time. The defendants then filed an affidavit with twenty-one exhibits, only one of which consisted of portions of the inventor's deposition. These submissions went well beyond those for which permission had been granted, and the district court declined to review the new material, explaining that it "was presumably available to them long before the hearing on the motion for summary judgment."

The district court examined the material that it deemed properly submitted in opposition to Biotec's motion for summary judgment of patent validity, including the opinion of the

³ **Fed. R. Civ. P. 56(f) When Affidavits are Unavailable.** Should it appear from the affidavits of a party opposing the motion that the party cannot for reasons stated present by affidavit facts essential to justify the party's opposition, the court may refuse the application for judgment or may order a continuance to permit affidavits to be obtained or depositions to be taken or discovery to be had or may make such other order as is just.

defendant's expert, Dr. Bastioli, that the patents were invalid. That opinion referred to two patents (the Lay reference and an Otey patent) that the expert stated were invalidating prior art.

The district court observed that the Lay reference issued after the filing date of the '777 patent and the "Otey patent" was not presented to the court. The district court remarked on the absence of explanation by the expert (who was not an attorney) as to why these references rendered the Biotec patents invalid. The court granted Biotec's motion for summary judgment that the patents were valid.

The defendants argue that they were under no obligation to explain their theories of invalidity. They state that the district court should have read the cited references and determined for itself whether they could invalidate the Biotec patents, that the district court "should have taken the time to give thoughtful consideration to material that left little doubt about the existence of significant questions of validity."

It is well established that conclusory statements of counsel or a witness that a patent is invalid do not raise a genuine issue of fact. See, e.g., Applied Companies v. United States, 144 F.3d 1470, 1475 (Fed. Cir. 1998) ("It is well settled that 'a conclusory statement on the ultimate issue does not create a genuine issue of fact.'"); Barmag Barmer Maschinenfabrik Ag. v. Murata Machinery, Ltd., 731 F.2d 831, 836, 221 USPQ 561, 564 (Fed. Cir. 1984) ("The party opposing the [summary judgment] motion must point to an evidentiary conflict created on the record at least by a counter statement of a fact or facts set forth in detail in an affidavit by a knowledgeable affiant. Mere denials or conclusory statements are insufficient.") It is not the trial judge's burden to search through lengthy technologic documents for possible evidence. The public interest in invalidating invalid patents does not override the well established procedure requiring the nonmovant to come forward with evidence sufficient to negate the movant's

position. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986) (party opposing the motion for summary judgment bears the burden of responding after the moving party has met its burden).

The defendants argue that since Biotec was the movant, in requesting summary judgment the burden was on Biotec to provide "more than a bare assertion that Defendants lacked sufficient evidence of invalidity." In Celotex, 477 U.S. at 323, the Court stated: "Of course, a party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." (quoting Fed. R. Civ. P. 56). Thus, argue defendants, they were under no obligation to come forward with any evidence unless Biotec had presented enough evidence of validity to shift the burden of coming forward to the defendants.

Biotec's motion contained more than a bare assertion of lack of evidence. Biotec presented deposition testimony of the defendants' primary witnesses wherein they admitted knowing no facts that implied the invalidity of the patents. In Celotex, 477 U.S. at 325, the Court explained that "the burden on the moving party may be discharged by 'showing' -- that is, pointing out to the district court -- that there is an absence of evidence to support the nonmoving party's case." Biotec states that it met this requirement at least in the Supplemental Reply Memorandum in the summary judgment proceedings, wherein Biotec discussed the evidence and theories of invalidity presented by the defendants. The defendants, in turn, state that they provided sufficient evidence of invalidity to withstand summary judgment. The district court rejected this argument, and granted Biotec's motion for judgment of validity.

On this appeal the defendants do not review in any detail the evidence that they assert invalidates the patents. The defendants do not distinguish between the evidence that was excluded from consideration by the district court and that which was included in the summary judgment record. Instead, the defendants argue that Dr. Bastioli "expressly mentioned" the Otey reference in her affidavit and that this mention, although presented without analysis, raised a material issue concerning patent validity. As we have discussed, the Bastioli statement of invalidity was properly viewed as inadequate by the district court. That an otherwise unexplained patent was "expressly mentioned" by the affiant does not provide the substance that precedent and practice require of summary judgment proceedings. See Celotex, supra.

Defendants also state that Biotec's motion for summary judgment related only to the issues of anticipation and obviousness, §§102 and 103, and that the court's grant of summary judgment that the patent was not invalid was improper because issues under §112 were raised in the defendant's motion for summary judgment. However, the defendants did not come forward with evidence sufficient to place validity under §112 in issue. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986) ("in the face of the defendant's properly supported motion for summary judgment, the plaintiff could not rest on his allegations of a conspiracy to get to a jury without 'any significant probative evidence tending to support the complaint.'") We have not been directed to a sufficient basis in the defendant's motion to support a ruling of patent invalidity on §112 grounds.

The defendants also argue that the district court abused its discretion in refusing to consider the later-filed affidavit and all of the accompanying exhibits, citing Cardinal Chemical Co. v. Morton International, Inc., 508 U.S. 83, 26 USPQ2d 1721 (1993), for its emphasis on the public interest in purging invalid patents. However, the district court acted within its authority in

its rejection of the tardy and unauthorized submissions under Rule 56(f). See, e.g., Abbott Laboratories v. Brennan, 952 F.2d 1346, 1351, 21 USPQ2d 1192, 1196 (Fed. Cir. 1991) ("It is improper on appeal to disturb a district court's trial management, absent a clear abuse of judicial discretion."); Friedrich v. Intel Corp., 181 F.3d 1105, 1110-11 (9th Cir. 1999) ("This court reviews the decision to admit or exclude evidence for an abuse of discretion.") (citing Jauregui v. City of Glendale, 852 F.2d 1128, 1132 (9th Cir.1988)); DeGrassi v. City of Glendora, 207 F.3d 636, 641 (9th Cir. 2000) ("We review the district court's ruling not to permit additional discovery pursuant to Federal Rule of Civil Procedure 56(f) for abuse of discretion.")⁴

The district court's judgment that the patents are not invalid is affirmed.

DAMAGES

The jury awarded Biotec damages of one million dollars, allocating three fourths of this amount to Novamont and one fourth to Biocorp. The defendants argue that the award was excessive in light of the amount of their sales in the United States, and presented evidence that Novamont's United States sales totaled approximately \$4.3 million, and Biocorp's sales were \$200,000.

In general, a jury's award of damages must be sustained unless "the amount is 'grossly excessive or monstrous', clearly not supported by the evidence, or based only on speculation or guesswork." Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1580, 24 USPQ2d 1401, 1419 (Fed. Cir. 1992) (citing Los Angeles Memorial Coliseum Commission v.

4 "On procedural issues not unique to the areas of law that are exclusively assigned to the Federal Circuit, the procedural law of the regional circuit is applied. Discovery under Rule 56(f) is of such a nature." Vivid Technologies, Inc. v. American Science & Engineering, Inc., 200 F.3d 795, 807, 53 USPQ2d 1289, 1297 (Fed. Cir. 1999). We thus look to Ninth Circuit procedural law for precedential guidance concerning practice under Rule 56(f).

National Football League, 791 F.2d 1356, 1360 (9th Cir. 1986)). See also, e.g., Fiskars, Inc. v. Hunt Manufacturing Co., 221 F.3d 1318, 1325, 55 USPQ2d 1569, 1575 (Fed. Cir. 2000) ("Damages assessed by a jury are largely discretionary with it. . . . To reverse the judgment of the trial court, the appellate court must conclude that the verdict was so 'gross' or 'monstrously excessive' that the trial court abused its discretion in permitting it to stand.") (quoting Smith v. Rowe, 761 F.2d 360, 368 (7th Cir. 1985)).

Biotec presented testimony that if it had licensed the patents it would have required an annual up-front license fee of about \$2.67 million, with a running royalty of no less than 5%. The defendants argued that these rates are unreasonable, and that no one had licensed the Biotec patents at these rates. Biotec states that Novamont's share of \$750,000 is equivalent to a royalty of 17.5% of its United States sales, on which the evidence showed a gross profit margin to Novamont of 40-42%. Biotec points to evidence that the value of Biocorp's distributorship was over two million dollars, countering Biocorp's argument that the jury's award exceeded Biocorp's total sales.

We conclude that on the evidence before the jury, applying the requisite standard of review of a jury assessment of damages, a reasonable jury could have reached the verdict that was rendered. That judgment must be affirmed.

THE CROSS APPEAL

Biotec appeals the jury's finding that Biocorp's infringement was not willful. Willfulness of infringement can incur multiplication of damages as well as an award of attorney fees. See 35 U.S.C. §§284, 285.

Biotec argues primarily that after the defendants were accused of infringement they failed to obtain an opinion of counsel as to either infringement or validity. Biocorp's Chairman

and CEO testified that he became aware of Biotec's patents when Biotec filed suit and again at his deposition, and admitted that he did not seek an opinion of counsel as to infringement or invalidity. He stated that he relied on the advice of Dr. Bastioli, a Novamont employee described as "a world-renowned expert in the art," who advised that neither Biocorp nor Novamont was infringing the Biotec patents. There was no other evidence on the issue of willfulness of infringement.

Biotec argues that on the totality of the circumstances the defendants' infringement was willful as a matter of law. However, "willful" action is quintessentially a question of fact, for it depends on findings of culpable intent and deliberate or negligent wrongdoing. Failure to obtain an opinion of counsel is relevant evidence, but does not automatically require a finding of willful infringement. All of the circumstances must be considered. In this case the jury could have placed weight on the reliance by the defendants on the technologic expertise and reputation of their advisor, and on the perceived closeness of the factual questions that required resolution by the jury. The jury's verdict that willful infringement was not proved could have been reached by a reasonable jury, and is sustained.

Conclusion

On the appeal and cross-appeal, the judgment is affirmed.

No costs.

AFFIRMED