United States Court of Appeals for the Federal Circuit

2007-1145, -1161

INNOGENETICS, N.V.,

Plaintiff-Cross Appellant,

v.

ABBOTT LABORATORIES,

Defendant-Appellant.

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Appealed from: United States District Court for the Western District of Wisconsin

Chief Judge Barbara B. Crabb

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Appeals from the United States District Court for the Western District of Wisconsin in case no. 05-CV-0575, Judge Barbara B. Crabb.

DECIDED: January 17, 2008

Before BRYSON, Circuit Judge, CLEVENGER, Senior Circuit Judge, and MOORE, Circuit Judge.

MOORE, Circuit Judge.

Abbott Laboratories (Abbott) appeals on a multitude of grounds the judgment entered against it by the United States District Court for the Western District of Wisconsin for infringement of Innogenetics, N.V.'s (Innogenetics) U.S. Patent No. 5,846,704 (the '704 patent). We reverse and remand for a new trial the district court's judgment as a matter of law that claim 1 of the '704 patent was not anticipated by U.S. Patent No. 5,580,718 (the Resnick patent). We also vacate the permanent injunction granted against Abbott. As for the whole host of other issues that Abbott raises on

appeal, we find no reversible error and affirm the lower court's judgment in those respects. Innogenetics cross-appeals the district court's judgment as a matter of law that Abbott's infringement was not willful. Under the standards recently articulated in In re Seagate Technology, LLC, 497 F.3d 1360 (Fed. Cir. 2007) (en banc), we also affirm that aspect of the lower court's judgment.

BACKGROUND

The technology in this case pertains to diagnostic tools that not only detect but also classify hepatitis C virus (HCV) genotypes in a biological sample, which facilitates tailoring the treatment of patients with different genotypes. The '704 patent claims a method of genotyping HCV based on distinct genetic sequences that can be found in the 5 prime untranslated region (5' UTR) of the HCV genome. This method teaches specifically hybridizing probes, or short strands of nucleic acids, to a target sequence in the 5' UTR via complementary base pairing principles, and then detecting the formation of any complexes formed between the probes and the nucleic acids of the 5' UTR.

Abbott's genotyping assay kits, like the method claimed in the '704 patent, also involve specifically hybridizing probes to the nucleic acids of the HCV's 5' UTR. The kits then detect the successful formation of any specifically hybridized complexes using the process of Realtime polymerase chain reaction (PCR). Through this process, dye molecules attached to Abbott's probes are released and observable as fluorescent signals after polymerase enzymes destroy the hybridized probe-target complexes.

Innogenetics sued Abbott, asserting that Abbott's genotyping assay kits infringe claims 1, 2, and 3 of the '704 patent. Claim 1, the only independent claim on appeal, reads in its entirety as follows:

> A method of genotyping HCV present in a biological sample comprising hybridizing nucleic acids in a biological sample with at least one probe and detecting a complex as formed with said probe and said nucleic acids of HCV, using a probe that specifically hybridizes to the domain extending from the nucleotides at positions -291 to -66 of the 5' untranslated region of the HCV.

'704 col.113 ll.1-7.

Abbott moved for summary judgment, asserting that its kits were not infringing, that the '704 patent was invalid, and that the '704 patent had been procured by inequitable conduct. In its order denying Abbott's motions, the district court construed the claim limitation "detecting a complex as formed" to mean "detecting a complex that is or has been formed." The district court also construed the limitation in the preamble, "method of genotyping," to mean "[a] method that distinguishes among types and/or subtypes of hepatitis C virus (HCV) and classifies the HCV into a genotype or subtype." On cross motions for summary judgment, the district court denied Abbott's motion and granted Innogenetics' motion, concluding that Abbott had failed to adduce sufficient evidence to require a trial on the issue of inequitable conduct. Furthermore, the district court deemed Abbott's inequitable conduct claim "exceptional" and awarded attorney's fees to Innogenetics.

At the final pre-trial conference, the district court granted Innogenetics' motion in limine and excluded testimony on obviousness by Abbott's witness, Dr. Patterson. However, the written order commemorating the conference rulings inaccurately stated that defendant was precluded from entering any evidence of obviousness at trial. Aware of the mistake, Abbott nonetheless never moved for correction or reconsideration of the written order, noting only that it wished to preserve an objection on the issue. Additionally, the district court precluded the following evidence related to anticipation:

1) U.S. Patent No. 6,071,693 (the Cha patent) on the grounds that Abbott did not disclose the patent as an anticipating prior art reference until the last day of discovery and 2) any testimony beyond the actual words and content of the Cha PCT application from Dr. Cha, the inventor of the Cha patent and the Cha PCT application, on the grounds that he had not been tendered as an expert witness and that an expert report had not been submitted.

Because Abbott conceded that its entire noninfringement argument had been predicated on a construction of the claims that the court had not adopted, the district court entered judgment as a matter of law of literal infringement against Abbott for literal infringement of claims 1, 2, and 3 of the '704 patent. The case then proceeded to a bifurcated jury trial with only Abbott's affirmative defense of anticipation tried during the liability phase. At trial, Abbott presented the international patent application for the invention claimed in the Cha patent and the testimony of its expert, Dr. Bruce Patterson, that the Resnick patent anticipated claim 1 of the '704 patent. However, before the case went to the jury, the district court granted judgment as a matter of law of no anticipation by the Resnick patent based on its determination that Dr. Patterson's testimony "rested on an inaccurate understanding of the construction of the limitation 'genotyping.'" The jury concluded that claim 1 of the '704 patent was not anticipated.[1] During the damages phase of trial, the jury awarded $7 million in damages to Innogenetics and found Abbott's infringement to be willful.

Post-trial, the district court denied Abbott's motion for a new trial on infringement and invalidity and for judgment as a matter of law or a new trial on damages. However,

[1] The jury did not decide the validity of claims 2 and 3, as they were dependent on claim 1.

the district court did grant Abbott's motion for judgment as a matter of law that infringement was not willful. The district court also granted Innogenetics' motion for a permanent injunction.

On appeal, Abbott challenges a myriad of issues, including the district court's claim construction, summary judgment of literal infringement, evidentiary exclusions as to Abbott's obviousness and anticipation defenses, judgment as a matter of law that the Resnick patent did not anticipate claim 1 of the '704 patent, summary judgment of no inequitable conduct, award of attorney's fees to Innogenetics for Abbott's counterclaim of inequitable conduct due to its exceptionality, and grant of a permanent injunction. On cross-appeal, Innogenetics challenges the district court's judgment as a matter of law overturning the jury verdict of willful infringement. We address each of these issues in turn.

ANALYSIS

I. INFRINGEMENT

A. Claim Construction

We begin our inquiry with the district court's claim construction, which we review de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). Abbott takes umbrage with the district court's construction of the two-letter word "as" from the claim limitation "detecting a complex as formed with said probe and said nucleic acids of HCV." According to Abbott, the word "as" limits the claims at issue to detecting hybridized complexes in a contemporaneous manner. Hence, Abbott asserts that its products are not encompassed by the '704 patent because they detect the formation of a hybridized complex through the observation of fluorescence emitted after

the complex has been destroyed, and not the actual complex itself. We conclude that the claim language makes no such distinction. Abbott's proposed construction unduly limits the claims of the '704 patent by divorcing the word "as" from its full context, "as formed with said probe and said nucleic acids of HCV." The district court properly construed the claim limitation as detecting the formation of probe-target complexes, regardless of whether the method of detecting requires destroying the probe-target complex itself.

In determining the meaning of a disputed claim limitation, we look primarily to the intrinsic evidence of record, examining the claim language, the written description, and the prosecution history. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). Words of a claim "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art. Id. at 1312-13. Claims are read in view of the specification, which is the single best guide to the meaning of disputed terms. Id. at 1315. "In examining the specification for proper context, however, this court will not at any time import limitations from the specification into the claims." CollegeNet, Inc. v. ApplyYourself, Inc., 418 F.3d 1225, 1231 (Fed. Cir. 2005) (citing Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1326 (Fed. Cir. 2002)).

A plain reading of the claim limitation suggests that it does just what it says—it detects the formation of a complex between a probe and nucleic acids of the HCV. Nowhere does the claim language suggest that it only detects the complex itself. Indeed, in an expert report submitted by Innogenetics, Dr. William Reznikoff, a molecular genetics expert, opined that, in the context of the entire patent and its prosecution history, one ordinarily skilled in the art would understand claim 1 to include

detecting any complexes that have been formed. Abbott provides no expert opinions on how a person ordinarily skilled in the art would have a different understanding of the claim limitation. Nor does Abbott ever contest the credibility of Dr. Reznikoff's understanding.

While we may not be in as able a position as the district court to ferret out the credibility of an expert, Dr. Reznikoff's reading is supported by the intrinsic evidence. The specification of the '704 patent explicitly states that the detection of hybrids "may be determined by means of colorimetric, fluorescent, radiometric detection or any other method comprised in the state of the art." '704 Patent col.6 ll.36-43 (emphasis added). Abbott contends that the written description constricts the claim limitation to a method of contemporaneous detection because the described embodiments all feature detection of an actual complex. However, as is well established, an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention. SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 (Fed. Cir. 1985). Given the sparse but broad statements in the specification about how the claimed invention detects hybridized complexes, see '704 Patent col.6 ll.36-43, col.20 ll.16-28, col.20 ll.41-42, Abbott's reading of the process of detection improperly narrows the claim language.

Lastly, relying on various dictionaries, Abbott argues that the word "as" is correctly defined as "at the same time that: while." Abbott's reliance on a single dictionary definition without explanation—especially where "as" has multiple meanings—commits the very error of construction that we warned against in Phillips. See 415 F.3d at 1321 ("The main problem with elevating the dictionary to such

prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim limitations within the context of the patent."). In context, the use of the word "as" is merely syntactical, linking the word "complex" to a description of its composition. See Merriam-Webster's Online Dictionary, http://www.m-w.com/dictionary/as (last visited Jan. 16, 2008) (defining "as" to mean "when considered in a specified form or relation—usually used before a preposition or a participle," as illustrated by the phrase, "my opinion as distinguished from his").

As the district court pointed out, there is little meaningful distinction between a method of detecting the hybridized complex itself and a method of detecting the hybridized complex through fluorescence emitted immediately after it is destroyed. What is detected is still a complex "formed with said probe and said nucleic acids of HCV." We uphold the district court's claim construction because it is consistent with our understanding of the claim limitation at issue.

B. Judgment as a Matter of Law of Literal Infringement

We affirm the JMOL entered against Abbott for literal infringement of claims 1, 2, and 3 of the '704 patent because it has not properly raised any plausible arguments on appeal. Given that the district court did not adopt Abbott's proposed claim construction, the sole defense against literal infringement asserted by Abbott was that Realtime PCR, the method of detection used in its assay kits, was not known to the ordinary artisan at the time of the filing of the '704 patent application. However, the district court deemed this issue forfeited because Abbott "did not raise this issue before trial when it could have been given thorough consideration. Instead it raised the issue for the first time at 9:30 p.m. on the night before the start of trial and did so simply by submitting a

proposed jury instruction, rather than by bringing the matter directly to the attention of the court and opposing counsel."

We review procedural issues not unique to patent law under regional circuit law. Bowling v. Hasbro, Inc., 403 F.3d 1373, 1375 (Fed. Cir. 2005). Absent extraordinary circumstances, the Seventh Circuit has stated that it rarely reaches forfeited arguments in civil litigation. Ocean Atl. Dev. Corp. v. Aurora Christian Sch., Inc., 322 F.3d 983, 1005 (7th Cir. 2003). Abbott's belief that "there was no need to raise [its argument] prior to the court adopting a claim construction not proposed by either party" falls well short of extraordinary. Accordingly, we affirm the district court's finding that Abbott had been fully heard on the issue of literal infringement and that there was no legally sufficient evidentiary basis for a reasonable jury to find for Abbott on that issue. See Fed. R. Civ. P. 50.

It should be noted that, forfeiture aside, Abbott's argument lacks merit. Essentially, Abbott argues that a patent can never be literally infringed by embodiments that did not exist at the time of filing. Our case law allows for after-arising technology to be captured within the literal scope of valid claims that are drafted broadly enough. See SuperGuide Corp. v. DirecTV Enters., Inc., 358 F.3d 870, 878-80 (Fed. Cir. 2004) (finding that the claim limitation "regularly received television signal" is broad enough to encompass digital signals even though no televisions that could receive digital signals existed as of the filing date).

Additionally, Abbott itself has put forth evidence that Realtime PCR did in fact exist by the time the inventors filed their PCT application in 1992, and by the time they applied for the '704 patent in 1994. In his expert report, Abbott's witness, Dr. Bruce

Patterson, stated that "Realtime PCR using 5' to 3' exonuclease activity was pioneered around 1991 . . . ." Abbott does not dispute this evidence. We have no reason to disturb the district court's grant of JMOL as to literal infringement.

II. INVALIDITY

Abbott challenges the district court's denial of its motion for a new trial on the issue of invalidity on a number of evidentiary exclusions. Regional circuit law governs our review of motions for a new trial. EMI Group N. Am., Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1348 (Fed. Cir. 2001). Under Seventh Circuit law, the district court's denial of a motion for a new trial is reviewed for abuse of discretion. See Naeem v. McKesson Drug Co., 444 F.3d 593, 605 (7th Cir. 2006). A new trial may be granted where "the verdict is against the weight of the evidence, the damages are excessive, or if for other reasons the trial was not fair to the moving party." Id. (internal quotations omitted). Evidentiary rulings are also reviewed for abuse of discretion. Wollenburg v. Comtech Mfg. Co., 201 F.3d 973, 977 (7th Cir. 2000) (citations omitted).

A. Obviousness

Abbott contends that it was clear error for the district court to preclude Abbott's obviousness defense. During the discovery period, the district court granted Innogenetics' motion to strike Dr. Patterson's supplemental expert report because it violated the court's earlier order on the filing of such supplemental reports. Abbott does not contest that ruling. This left Abbott with only Dr. Patterson's original expert report for his planned testimony on obviousness. The district court determined that the report was insufficient to support a jury finding of obviousness and thus failed the requirements of Federal Rule of Civil Procedure 26(a). Therefore, at the final pretrial conference, it

granted Innogenetics' motion in limine, and excluded Dr. Patterson from testifying about obviousness at trial.

However, the written order commemorating the conference rulings inaccurately stated that defendant was precluded from entering any evidence of obviousness at trial. Aware of the mistake, Abbott nonetheless never moved for correction or reconsideration of the written order. Instead, it advised plaintiff's counsel in writing that it would not be contesting the written ruling and would put in no evidence of obviousness. Abbott confirmed this decision on the first day of trial, noting only that it wished to preserve an objection on the issue. Post-trial, the district court denied Abbott's Rule 50(b) motion for a new trial on obviousness because Abbott, despite its knowledge from the very beginning that the written order was inaccurate, was only then seeking correction by way of overturning the jury's unfavorable verdict against it. Abbott now appeals the district court's denial of its motion for a new trial on obviousness on the grounds that Dr. Patterson's testimony on the issue was excluded and that, furthermore, no other evidence on the issue was allowed. Because the district court's rulings were not an abuse of discretion, we leave the jury verdict intact.

1. Dr. Patterson's testimony

The district court did not err in finding that Dr. Patterson's report on the alleged obviousness of the asserted claims of the '704 patent was deficient for purposes of disclosure under Rule 26. For each of the claims that he analyzes for obviousness, Dr. Patterson merely lists a number of prior art references and then concludes with the stock phrase "to one skilled in the art it would have been obvious to perform the

genotyping method in [claims 1-9 & 12-13] of the '704 patent."[2] "[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006); see also KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1741 (2007) ("To facilitate review, this analysis should be made explicit.") (citing Kahn, 441 F.3d at 988). Nowhere does Dr. Patterson state how or why a person ordinarily skilled in the art would have found the claims of the '704 patent obvious in light of some combination of those particular references. As the district court found: "It is not credible to think that a lay jury could examine the Cha application, the Resnick '718 patent that defendant cited as prior art or any of the other references and determine on its own whether there were differences among them and the '704 patent." Innogenetics, N.V. v. Abbott Labs., No. 05-C-0575-C, slip op. at 14 (W.D. Wis. Jan. 3, 2007). Such vague testimony would not have been helpful to a lay jury in avoiding the pitfalls of hindsight that belie a determination of obviousness. See Graham v. John Deere Co., 383 U.S. 1, 36 (1966) (discussing the "importance of guarding against hindsight . . . and resist[ing] the temptation to read into the prior art the teachings of the invention in issue" when considering the obviousness of a patent).

[2] Abbott argues on appeal that Dr. Patterson "also opined that the Cha PCT application standing alone rendered the '704 patent obvious." For support, Abbott cites to a portion of Dr. Patterson's report, Section VIII-A, which discusses in some detail the Cha PCT application. However, this section of the report focuses exclusively on anticipation. Even if we expand our consideration to the entire expert report, Dr. Patterson never once opines that the claims of the '704 patent are rendered obvious by the Cha PCT application alone. To the extent that Dr. Patterson does opine on obviousness, in each instance in which he references the Cha PCT application, it is always in combination with other references. We therefore conclude that the district court did not abuse its discretion in excluding Dr. Patterson from testifying at trial that the Cha PCT application alone renders the '704 patent claims obvious.

On appeal, Abbott argues in a single sentence, without any explanation, that the district court erred in concluding that Dr. Patterson did not offer any evidence of a "motivation to combine" the various prior art references that he opined rendered the claims of the '704 patent obvious. To be sure, Dr. Patterson suggested that one of skill in the art was motivated to find a method capable of genotyping because at least one prior art reference had disclosed that "different genotypes of HCV respond differently to interferon therapy." The district court was nevertheless correct that knowledge of a problem and motivation to solve it are entirely different from motivation to combine particular references to reach the particular claimed method. Innogenetics, slip op. at 14 ("A generalized motivation to develop a method is not the kind of motivation required by the patent laws."). We cannot conclude that the district court abused its discretion when it precluded Dr. Patterson's vague and conclusory obviousness testimony which did not offer any motivation for one skilled in the art to combine the particular references he cites in order to practice the claimed method.[3]

Abbott also argues that there is no requirement that an expert opine on motivation to combine references, and that motivation can be established by other witnesses or the prior art. Abbott is correct that an expert is not the only source for

[3] We are mindful that in KSR, the Supreme Court made clear that a finding of teaching, suggestion, or motivation to combine is not a "rigid rule that limits the obviousness inquiry." 127 S. Ct. at 1741. This, however, does not alter the district court's pre-KSR conclusion in this case or our affirmance thereof. There was a complete absence of any proof that one skilled in the art would find the particular claimed method obvious based upon Dr. Patterson's list of prior art references or the knowledge generally available to those of ordinary skill in the art for any reason. We must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention. Although Abbott cites KSR, it does not argue on appeal that a different result would be reached in this case under KSR.

evidence that it would be obvious for one skilled in the art to combine references to reach the claimed method. But, as the district court held, "some kind of motivation must be shown from some source, so that the jury can understand why a person of ordinary skill would have thought of either combining two or more references or modifying one to achieve the patented method." Id. at 13. However, as we discuss in the next section, Abbott was precluded from offering any other evidence of obviousness, due to Abbott's own failure to notify the district court of its error in its preclusion order, and this determination was not an abuse of discretion.

2. Preclusion of all evidence of obviousness

Even in the face of the inaccurate preclusion order, we conclude that the district court's denial of a new trial on the issue of obviousness was well within its discretion. In the Seventh Circuit, a new trial is granted "only when the record shows that the jury's verdict resulted in a miscarriage of justice or where the verdict, on the record, cries out to be overturned or shocks our conscience." Latino v. Kaizer, 58 F.3d 310, 314 (7th Cir. 1995) (internal quotations omitted). This is hardly a case that cries out to be overturned or shocks our conscience. In its opening brief, Abbott's only support for its argument that it had suffered prejudice from not being able to present other witnesses on obviousness is the bald statement that some of its other non-expert witnesses "could have" established invalidity under § 103. Speculation is not sufficient to demonstrate prejudice. The district court found, and our review of the record does not show otherwise, that Abbott "[said] nothing about what these witnesses would have had to say about obviousness" in specific. Innogenetics, slip op. at 16 ("Without such information, I cannot determine whether defendant was prejudiced by not being

permitted to adduce evidence on obviousness."). Without having provided any satisfactory explanation as to why it waited until the conclusion of trial to alert the court to the inaccurate order, Abbott will have to bear the cost of being precluded from presenting any evidence of obviousness at trial. For the above reasons, the district court did not abuse its discretion denying Abbott a new trial on the issue of obviousness.

B. Anticipation

1. Dr. Cha's testimony

For purposes of showing that the claims of the '704 patent were anticipated by prior art and thus invalid, Abbott sought to introduce at trial the testimony of Dr. Tai-An Cha, the inventor and author of three prior art references, including the Cha PCT application, which was before the jury. The district court confined Dr. Cha's testimony to the actual words and content of the Cha PCT application because an expert report was required even though Abbott had only disclosed Dr. Cha as "a fact witness and, pursuant to Fed. R. Civ. P. 26(a)(2)(A), as an expert who had not been specially retained." The district court concluded that, given Dr. Cha's role as the inventor behind the application, the mere fact that he was not receiving compensation for his scientific testimony did not exempt Abbott from furnishing an expert report. Without information about the proposed content of Dr. Cha's de facto expert testimony, Innogenetics would not have been able to prepare an adequate deposition or cross-examination.

On appeal, Abbott contends that "[t]here is no requirement that a retained expert, rather than the prior art's author, provide [an explanation of how the ordinary artisan would have understood a reference's disclosures.]" Abbott entirely fails to address the

district court's reason for restricting Dr. Cha's testimony—that witnesses who will be giving scientific testimony are not exempt from the report requirements of Rule 26(a)(2)(B), even when they are not compensated for their work. In sum, the district court concluded that Abbott should have provided an expert report to Innogenetics for Dr. Cha's specialized testimony. The Seventh Circuit has expressly left open the question of whether experts not specially retained but providing scientific testimony must comply with Rule 26(a)(2)(B), see Musser v. Gentiva Health Servs., 356 F.3d 751, 758 n.3 (7th Cir. 2004), and we need not reach this issue since Abbott has not challenged this determination.

The district court also concluded that Dr. Cha's testimony should be limited because any information he might have to offer beyond the words of the Cha PCT application would be irrelevant to the issue before the jury of "whether the Cha [PCT] application was sufficient in itself to have informed a person of ordinary skill in the art in 1992 how to distinguish among HCV genotypes by using probes in the 5' UTR." As the inventor behind the Cha PCT application, Dr. Cha could have added information that might not have been understood by a person of ordinary skill in the art just from reading the application, such as the conditions he used for his experiments or explanations for anomalous results. Again, Abbott fails to address the district court's reasoning or discuss how Dr. Cha's testimony would inform the jury of how the ordinary artisan would understand the disclosures of the Cha PCT application. Therefore, we affirm the district court's evidentiary ruling because it was not an abuse of its discretion.

2. The Cha patent

Abbott did not disclose the Cha patent as an anticipatory prior art reference under 35 U.S.C. § 282 until the last day of discovery, after the time for depositions had passed. Abbott had not discussed the Cha patent in an expert report, identified it during discovery in response to Innogenetics' interrogatories on anticipation, or mentioned it in the final pretrial conference. Abbott did not refer to the Cha patent again until the eve of trial, when Abbott sought to amend the district court's jury instructions to include the Cha patent in the jury instructions specific to anticipation. Finding that the belated introduction of the Cha patent as an anticipatory prior art reference was prejudicial to Innogenetics, the district court excluded the Cha patent from consideration on the issue of anticipation.

Although Abbott technically complied with the requirements of § 282, the district court did not abuse its discretion in excluding the Cha patent from trial. Abbott's disclosure of the Cha patent as an anticipatory prior art reference on the very last day of discovery meant Innogenetics was stripped of any meaningful opportunity to prepare an adequate cross-examination of the reference. See ATD Corp. v. Lydall, Inc., 159 F.3d 534, 551 (Fed. Cir. 1998) ("The purpose of § 282, like that of the Federal Rules, is to prevent unfair and prejudicial surprise, not to facilitate last-minute production of evidence."). That Innogenetics had an expert analyze the Cha patent in the context of inequitable conduct does not mean, as Abbott would have us believe, that Abbott's late disclosure did not prejudice Innogenetics on the issue of validity under § 102. The district court did not abuse its discretion in precluding the Cha patent.[4]

[4] This case aptly demonstrates the pitfalls of playing fast and loose with rules of discovery. Conclusory expert reports, eleventh hour disclosures, and attempts to proffer expert testimony without compliance with Rule 26 violate both the rules and

3. JMOL of no anticipation by the Resnick patent

Abbott argues on appeal that the district court erred in granting JMOL of no anticipation of claim 1 of the '704 patent by the Resnick patent and in denying its motion for a new trial on the same basis.[5] The district court's grant of JMOL was predicated on its determination that Dr. Patterson's testimony with regard to anticipation by the Resnick patent "rested on an inaccurate understanding of the construction of the term 'genotyping.'" Innogenetics, slip op. at 29.

This determination by the district court, that Dr. Patterson's testimony was tainted by an inaccurate understanding of the claim term genotyping, is clearly erroneous. At trial, Dr. Patterson testified on behalf of Abbott that the Resnick patent anticipated claim 1 of the '704 patent. Specifically, he stated that the Resnick patent disclosed probes that "distinguish" between two groups of hepatitis C isolates—"one containing hepatitis C 1 . . . [and] the non-1 types of hepatitis C." Opposing counsel objected, arguing that Dr. Patterson's use of the word "distinguish" at trial was inappropriate because his expert report submitted under Rule 26 defined a "method of genotyping" as "the process of detecting and classifying the different strains of the virus as manifested by nucleotide sequence variation in a certain region of the virus genome. In other words, genotyping

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principles of discovery, and the obligations lawyers have to the court. Exclusion and forfeiture are appropriate consequences to avoid repeated occurrences of such manipulation of the litigation process.

[5] Abbott additionally seeks to overturn the district court's judgment as a matter of law of no anticipation by the Resnick patent of claim 2 of the '704 patent. However, Abbott never presented this argument at trial or even during discovery. We will not decide an issue raised for the first time on appeal. Taubenfeld v. AON Corp., 415 F.3d 597, 599 (7th Cir. 2005) (citing Heller v. Equitable Life Assurance Soc'y, 833 F.2d 1253, 1261-62 (7th Cir. 1987)) ("On numerous occasions we have held that if a party fails to press an argument before the district court, he waives the right to present that argument on appeal.").

detects and classifies the various genotypes of a virus, such as, in the case of HCV, HCV-1, HCV-2, HCV-3, HCV-4, HCV-5, and HCV-6." Docket. No. 33 (Patterson Expert Rep. 4).

The dispute over whether Dr. Patterson based his testimony on the district court's claim construction seems to turn upon his use of the words "detect" and "classify" and the district court's use of the words "distinguish" and "classify" in its construction of a "method of genotyping" as "[a] method that distinguishes among types and/or subtypes of hepatitis C virus (HCV) and classifies the HCV into a genotype or subtype." Despite the difference in semantics, we discern no difference in meaning between the definition of genotyping used by Dr. Patterson and the one adopted by the district court.

The '704 patent, by its own terms, differs from the prior art in its ability not just to detect the presence of HCV, but more importantly, to identify the types and/or subtypes of HCV that exist in a sample. The specification of the '704 patent states:

> Several patent applications have addressed the problem of detecting the presence of HCV . . . . Furthermore, the 5' UR of HCV isolates has been proven to be a good candidate for designing probes and primers for general HCV detection . . . . However, none of these patent applications presents a method of identifying the type and/or subtype of HCV present in the sample to be analyzed. . . . Consequently, the aim of the present invention is to provide a method for the rapid and indisputable determination of the presence of <u>one or several</u> genotypes of HCV present in a biological sample and indisputably classifying the determined <u>isolate(s)</u>.

'704 Patent col.2 ll.7-43 (emphasis added). As disclosed, the method of genotyping in the '704 patent requires more than simply determining whether HCV is present (i.e., detecting HCV) in a sample. It requires detecting HCV, and then distinguishing among one or more of the types and/or subtypes of HCV and being able to classify the types

and/or subtypes found. Certainly, one of the preferred embodiments of the '704 patent is capable of distinguishing among all six presently known types of HCV using multiple probes. '704 Patent col.10 ll.5-10.

To the extent, however, that Innogenetics argues that a "method of genotyping" requires identifying both the presence and the absence of types in a sample and thereby distinguishing among all six types of HCV, it is in error. (Oral Arg. Tr. 28:03-28:33, Oct. 1, 2007) ("[I]t's the ability to exclude . . . it's the ability to say I know what I have and I know what I don't have . . . you may or may not be able to say that you don't have something else that is in the contaminated sample . . . you might be able to say I got type A and type B, but you can't say a negative, that I don't have type 1-C or type 1-D . . . ."). Claim 1 is not so narrow as to require a method capable of identifying every possible genotype of HCV present and absent in a sample. In fact, claim 1 states that the claimed "method of genotyping" may be performed with "at least one probe." This contemplates infringement by a method that uses a single probe to detect and classify the presence of a single type of HCV. A single probe would not be capable of identifying what genotypes are present along with what genotypes are not present in a sample (a single probe could not distinguish and classify all six types). In short, the "method of genotyping" in claim 1 covers a method capable of detecting and classifying at least one particular type of HCV without necessarily identifying the absence of all other types. This is the only definition consistent with the language of the claim itself and is supported by the written description.

In this respect, Dr. Patterson's expert report and trial testimony are both consistent with the construction of "method of genotyping." In his expert report, Dr.

Patterson stated that the Resnick patent is capable of "detecting and classifying types of HCV." Docket No. 33 (Patterson Expert Rep. 19). At trial, contradicting the testimony of Innogenetics' witnesses, he testified that the Resnick patent "distinguish[es]" between two groups of HCV, type 1 HCV and all other types of HCV. (Trial Tr. vol. 3, 23:19-24:4, Aug. 29, 2006). Dr. Patterson's reading of the Resnick patent was that it disclosed a method capable of identifying whether a sample contained HCV type 1 as opposed to another type of HCV. If true, this would meet the "method of genotyping" limitation of claim 1.[6] Dr. Patterson's failure to use the district court's exact words does not change the substance of his testimony or render it inapplicable.

We therefore find improper the district court's preclusion of Dr. Patterson's testimony on the basis that he was using a different definition of "method of genotyping." Accordingly, we reverse the district court's entry of JMOL and remand for a new trial on the issue of whether the Resnick patent anticipated claim 1 of the '704 patent consistent with this opinion.

III. INEQUITABLE CONDUCT

We review summary judgment decisions de novo, reapplying the standard used by the district court. Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc., 389 F.3d 1370, 1376 (Fed. Cir. 2004); Steen v. Myers, 486 F.3d 1017, 1021 (7th Cir. 2007). Under that standard, summary judgment must be granted when, drawing all

[6] Innogenetics may have other arguments or contradictory evidence with regard to whether the Resnick patent anticipates. We decide only that, in light of the proper construction of a "method of genotyping," it was an abuse of discretion for the district court to preclude Dr. Patterson's testimony on the Resnick patent and to grant JMOL. What a prior art reference discloses is, of course, a question of fact, and if there are disputes over material facts, whether the Resnick patent anticipates claim 1 of the '704 patent should be resolved at trial by the fact finder.

reasonable inferences in favor of the non-movant, there is no genuine issue as to any material fact and no reasonable jury could return a verdict for the non-movant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

"[I]nequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." Pharmacia Corp. v. Par Pharm., Inc., 417 F.3d 1369, 1373 (Fed. Cir. 2005) (quoting Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995)). Materiality is defined by what a reasonable examiner would have considered important in deciding whether to allow a patent application. Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1316 (Fed. Cir. 2006). Both intent and materiality are questions of fact, and must be proven by clear and convincing evidence. Young v. Lumenis, Inc., 492 F.3d 1336, 1344 (Fed. Cir. 2007) (citing J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1559 (Fed. Cir. 1984)).

Abbott contends that Innogenetics' representation to the PTO of the relevance of the Cha PCT application during the prosecution of the '704 patent amounts to inequitable conduct. Prior to applying for the '704 patent ('568 application), the inventors of the claimed method of genotyping filed for a patent (EP '342 application) in the European Patent Office (EPO). The EP '342 application was prosecuted under a "problem solution" framework common in European practice in which a piece of art (whether relevant or not) is termed the "closest prior art." The prosecuting attorney identified the Cha PCT application as the closest prior art, but argued that none of the submitted references taught or disclosed the method claimed in the EP '342 application. Under its standards of patentability, the EPO determined that certain claims in the EP

’342 application were not novel in light of the Cha PCT application. Thus, claims were amended with a disclaimer that they were “amended to disclaim the teaching of [the Cha PCT application.]” The prosecution history of the ’704 patent indisputably shows that Innogenetics submitted as prior art references to the PTO both the Cha PCT application itself and an international search report that clearly marked the Cha PCT application as problematic for the EPO. However, Innogenetics’ patent attorney, in his accompanying prior art statement submitted to the PTO, stated that “the references do not relate to the invention and, therefore, further discussion of the same is not necessary.” In direct contrast to the statement made to the PTO, Innogenetics’ prosecuting attorney admitted that he did not actually examine the prior art identified, and that his statement that “the references do not relate to the invention” was the same boilerplate language he used in other prior art statements.

The district court correctly concluded that Innogenetics’ behavior before the PTO did not constitute a material omission or misrepresentation. Innogenetics’ representation of the Cha PCT application amounted to mere attorney argument and our precedent has made clear that an applicant is free to advocate its interpretation of its claims and the teachings of prior art. See Life Techs., Inc. v. Clontech Labs., Inc., 224 F.3d 1320, 1326 (Fed. Cir. 2000). Cases involving affidavits or declarations are held to a higher standard. See, e.g., eSpeed, Inc. v. Brokertec USA, LLC, 480 F.3d 1129, 1136 (Fed. Cir. 2007) (explaining that false statements made by patentees in sworn declarations or affidavits, as opposed to attorney argument, are “inherently material”). Given that the Cha PCT application had been submitted for the patent

examiner to examine herself, she was free to accept or reject the patentee's arguments distinguishing its invention from the prior art.

Abbott has failed to demonstrate any genuine issue of material fact as to the materiality of Innogenetics' representation and therefore we affirm the district court's grant of summary judgment of no inequitable conduct. We also affirm the district court's award of attorney's fees based upon its finding that the claim of inequitable conduct was exceptional. We see no clear error in this determination.

IV. PERMANENT INJUNCTION

We review the district court's decision to grant the permanent injunction for abuse of discretion. Joy Techs., Inc. v. Flakt, Inc., 6 F.3d 770, 772 (Fed. Cir. 1993). We may find an abuse of discretion on a showing "that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings." Id. An injunction does not necessarily follow a determination that a patent has been infringed. eBay, Inc. v. MercExchange, LLC, 126 S. Ct. 1837, 1840 (2006). Rather, whether an injunction is warranted in a patent case is to be determined, as in other cases, according to the well established four part test. Id. at 1839.

Abbott contends that the district court clearly erred in its finding that Innogenetics had been irreparably harmed and was not adequately remedied by the $7 million award of damages for Abbott's infringement. It argues that, because the jury included a market entry fee of $5.8 million in its calculation of damages, Innogenetics has been fully compensated for both Abbott's past infringement and possible future sales of its accused products.

At the damages phase of trial, the jury was instructed to calculate a reasonable royalty for Abbott's infringement of the '704 patent starting from "just before the infringement began (in June 2003)." Docket No. 359 (Jury Instructions 3). Nowhere did the jury instructions state the reasonable royalty would be limited to a period from the start of infringement to the date of judgment. In fact, the jury was told that a reasonable royalty could "include both an up-front payment and an ongoing royalty payment." Docket No. 359 (Jury Instructions 1) (emphasis added).

Innogenetics conceded at oral argument that the final amount of damages awarded by the jury included both a market entry fee of $5.8 million and an ongoing royalty payment amount of $1.2 million. The jury's damage award exactly tracked damages proposed by Innogenetics' expert, John Jarosz, at trial—$7 million, which included an upfront payment that equated to approximately $5.8 million and a running royalty of 5 to 10 Euros per test on the 190,000 tests Abbott had sold up to that point. Docket No. 340 (Trial Tr. vol. 2, 9:15-10:8, Sept. 5, 2006). Contrary to Innogenetics' contentions, the jury verdict of $7 million was not a royalty for Abbott's past infringement only.[7] The record is replete with references to the market entry fee as an amount paid in anticipation of Abbott's long-term license to sell its products. For example, Mr. Jarosz, testified that the hypothetical negotiation upon which he was basing his proposed amount of damages was not capped by the date of the jury award, but would

[7] It is hard to believe that a hypothetical negotiation between Innogenetics and Abbott would result in a royalty of $7 million that included a market entry fee of $5.8 million to sell licensed products for a three year period only, Abbott's total revenue during the period of infringement was just $13 million. State Contr. & Eng'g Corp. v. Condotte Am., Inc., 346 F.3d 1057, 1072 (Fed. Cir. 2003) ("[A]n actual infringer's profit margin can be relevant to the determination of a royalty rate in a hypothetical negotiation.") (citing Interactive Pictures Corp. v. Infinite Pictures, Inc., 274 F.3d 1371, 1385 (Fed. Cir. 2001)).

have involved looking at "what, over a longer term, would be a sensible license." Docket No. 340 (Trial Tr. vol. 2, 18:21-22, Sept. 5, 2006.) Having used Innogenetics' licensing agreement with Roche as a template for his calculations for this case, Mr. Jarosz also testified that one of the reasons Roche entered a deal for an upfront market entry fee of $6 million plus a running royalty is that "the long run is what drove its licensing perspective." Docket No. 340 (Trial Tr. vol. 2, 18:22-19:2, Sept. 5, 2006). See also Docket No. 223 (Jarosz Video Dep. 115:12-116:25, July 27, 2006) (explaining that the damage award contemplates an upfront fee, the calculation of which is based upon projected sales until 2019, and a running royalty); Docket No. 229 (Jarosz Expert Rep. 34-35) (explaining that his $5.8 million market entry fee was based upon "projected sales of its HCV genotyping tests through 2019").

The reasonable royalties awarded to Innogenetics include an upfront entry fee that contemplates or is based upon future sales by Abbott in a long term market. When a patentee requests and receives such compensation, it cannot be heard to complain that it will be irreparably harmed by future sales. Moreover, this factor greatly outweighs the other eBay factors in this case. As a result, the district court's grant of an injunction prohibiting future sales of Abbott's genotyping assay kits was an abuse of discretion and must be vacated.[8] While the market entry fee was based upon the projection that

[8] In its order granting the permanent injunction, the district court stated that "[i]t would denigrate the value of plaintiff's patent rights to allow defendant to continue to sell plaintiff's invention as its own in exchange for the same fee it would have paid without a lawsuit." Injunctive relief ought not to act as a form of "extra damages" to compensate for litigation costs. See Amstar Corp. v. Envirotech Corp., 823 F.2d 1538, 1549 (Fed. Cir. 1987) (remarking that injunctions may not be punitive in any case). Cf. Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1581 (Fed. Cir. 1996) (finding that awarding "kickers" on top of a reasonable royalty to compensate for heavy litigation costs or expenses is abuse of discretion). If litigation costs were a factor, injunctive relief would

Abbott could sell its product through 2019, even Abbott acknowledges that such future sales would be subject to the running royalty, a compulsory license. We remand to the district court to delineate the terms of the compulsory license, such as conditioning the future sales of the infringing products on payment of the running royalty, the 5-10 Euros per genotyping assay kit.[9]

V. JMOL of No Willful Infringement

Finally, we turn to Innogenetics' cross-appeal challenging the district court's grant of JMOL, overturning the jury's verdict of willful infringement. Under the standard recently articulated in In re Seagate Tech., LLC, "proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness." 497 F.3d at 1371. "[T]o establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." Id. "[T]he patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." Id. Our review of the record does not indicate how Abbott's development and sale of its genotyping products were at risk of an objectively high likelihood of infringement. Accordingly, we affirm the lower court's grant of JMOL of no willful infringement.

CONCLUSION

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be warranted in every litigated patent case. Cf. eBay, 126 S. Ct. at 1840 (noting that permanent injunctions are not to be granted as a matter of course in patent litigation).

[9] An injunction delineating the terms of the compulsory license would permit the court to retain jurisdiction to ensure the terms of the compulsory license are complied with.

For the foregoing reasons, the judgment of the United States District Court for the Western District of Wisconsin is affirmed-in-part, reversed-in-part, and vacated-in-part. The case is remanded for further proceedings in accordance with this opinion.

AFFIRMED-IN-PART; REVERSED-IN-PART; VACATED-IN-PART; and REMANDED

COSTS

No costs.