NOTE: This disposition is nonprecedential.

# United States Court of Appeals for the Federal Circuit

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**DURAMED PHARMACEUTICALS, INC.,**
*Plaintiff-Appellee,*

**v.**

**WATSON LABORATORIES, INC.,**
*Defendant-Appellant.*

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2010-1331

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Appeal from the United States District Court for the District of Nevada in Case No. 08-CV-0116, Judge Larry R. Hicks.

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Decided: March 25, 2011

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ALEXANDER F. MACKINNON, Kirkland & Ellis LLP, of Los Angeles, California, argued for plaintiff-appellee. With him on the brief was ROBERT G. KRUPKA. Of counsel on the brief were CHARANJIT BRAHMA, COREY J. MANLEY and J. JOHN LEE, of Washington, DC.

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TOMPKINS; KENNETH E. JENKINS, of San Diego, California; CEDRIC C.Y. TAN and KRISTIN M. COOKLIN, of Washington, DC.

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Before LOURIE, LINN, and DYK, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Watson Laboratories, Inc. ("Watson") appeals from the decision of the United States District Court for the District of Nevada, holding on summary judgment that the asserted claims of U.S. Patent 7,320,969 ("the '969 patent") were not invalid for obviousness. *Duramed Pharms., Inc. v. Watson Labs., Inc.*, 701 F. Supp. 2d 1163, 1167-71 (D. Nev. 2010). Watson also appeals the district court's exclusion of its expert's testimony on prior use of the claimed invention. *Id.* at 1166-67. Because the district court erred in its determination of nonobviousness, but did not abuse its discretion in excluding certain expert testimony, we *reverse in part*, *affirm in part*, and *remand*.

## BACKGROUND

Duramed Pharmaceuticals, Inc. ("Duramed") owns the '969 patent, which covers an extended-cycle combined oral contraceptive ("COC") regimen commercialized by Duramed as Seasonique®. Unlike traditional 28-day COC regimens, in which estrogen- and progestin-containing pills are administered for 21 days and hormone-free pills for 7 days, extended-cycle regimens increase the menstrual cycle's natural length by administering hormone-containing pills for greater than 21 days. Extended-cycle regimens thus postpone estrogen-withdrawal symptoms experienced by many women during the hormone-free period. The incidence of estrogen-withdrawal symptoms can also be reduced by administering low dosages of

estrogen during the traditional hormone-free period. Duramed's Seasonique® combines an extended-cycle COC regimen with the administration of low-dose, unopposed estrogen during the hormone-free period. Specifically, the regimen consists of 84 daily pills containing 30 µg of the estrogen ethinyl estradiol and 150 µg of the progestin levonorgestrel, followed by 7 daily pills containing 10 µg of ethinyl estradiol only.

On March 6, 2008, Duramed brought suit against Watson under 35 U.S.C. § 271(e)(2) after Watson filed an Abbreviated New Drug Application ("ANDA") seeking Food and Drug Administration ("FDA") approval for a generic version of Seasonique®. Duramed alleged infringement of claims 1-9, 15, and 17-19 of the '969 patent. Claim 19 is representative:

> 19. A method of contraception in a female in need thereof the method comprising administering to the female a dosage comprising a combination of estrogen and progestin for a period of 84 consecutive days, followed by administration of a dosage consisting essentially of estrogen for a period of 7 consecutive days,
>
> wherein the estrogen that is administered in combination with progestin for the period of 84 consecutive days is orally administered monophasicly in a daily amount of about 30 µg of ethinyl estradiol,
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> the estrogen that is administered for the period of 7 consecutive days is orally administered monophasicly in a daily amount of about 10 µg of ethinyl estradiol, and
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> the progestin that is administered in combination with estrogen for the period

> of 84 consecutive days is orally administered monophasicly in a daily amount of about 150 µg of levonorgestrel.

'969 patent claim 19. The '969 patent issued on January 22, 2008, and claims priority back to an application filed on December 5, 2001.

Watson stipulated to infringement but challenged the '969 patent's validity under 35 U.S.C. § 103. In making its obviousness challenge, Watson relied on, *inter alia*, (1) a 1994 Kovacs article, which describes an extended-cycle COC regimen of 84 daily pills containing 30 µg ethinyl estradiol and 150 µg levonorgestrel, followed by 7 daily hormone-free pills; (2) U.S. Patent 6,027,749 ("the '749 patent"), which discloses COC regimens of up to 77 daily pills containing 15-20 µg ethinyl estradiol and 50-125 µg levonorgestrel, followed by 7 daily pills containing 10-15 µg ethinyl estradiol to reduce the incidence of premenstrual headaches; and (3) two Sulak articles from 1997 and 2000, which describe the problem of headaches resulting from estrogen withdrawal as well as the use of low-dose, estrogen-only pills during the hormone-free period as a way to alleviate such headaches.

Watson's expert witness, Dr. Michael A. Thomas, opined on the teachings of these prior art references. He also opined that one of skill in the art would have been motivated to combine the Kovacs COC regimen with the 7 days of unopposed estrogen as claimed in the '969 patent because the Kovacs article recognized that the regimen may result in headaches in some women. J.A. 824-25. In addition, Dr. Thomas testified that he had personally prescribed the contraceptive regimen claimed in the '969 patent prior to the patent's priority date, December 5, 2001. The district court granted Duramed's motion to

exclude Thomas's testimony regarding this prior use as uncorroborated. *Duramed*, 701 F. Supp. 2d at 1166-67.

The district court also granted summary judgment of nonobviousness. The court analyzed Watson's "three most significant" prior art references, the Kovacs article, the Sulak article,[1] and the '749 patent, finding the remaining art "cumulative." *Id.* at 1168 n.3. Regarding the Kovacs article, the court found that it did not provide support for combining 84 daily hormone pills with 7 days of unopposed estrogen to alleviate estrogen-withdrawal symptoms because it describes headaches throughout the menstrual cycle and fails to make any mention of using unopposed estrogen. *Id.* at 1168-69. Regarding the Sulak articles, the court found that, although they identify headaches as a symptom of hormone withdrawal, they mention the addition of unopposed estrogen only as a theoretical, untested solution. *Id.* at 1169-70. Regarding the '749 patent, the court found that by disclosing a variety of COC regimens, the patent did not establish consistent knowledge in the community, and that it provided no basis for adding estrogen-only pills to the end of a COC regimen to alleviate withdrawal headaches. *Id.* at 1170. Finally, the court found that Watson's expert, Thomas, was not a person of ordinary skill in the art, but rather an active participant in research in the field of endocrinology. *Id.*

Watson appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

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[1] The district court cites the 1997 Sulak article, but it appears to have relied on a combination of the 1997 and 2000 Sulak articles. Accordingly, we refer to these articles together as the Sulak articles.

## DISCUSSION

This court reviews a district court's decision on summary judgment *de novo*, reapplying the same standard applied by the district court. *Iovate Health Scis., Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*, 586 F.3d 1376, 1380 (Fed. Cir. 2009). Summary judgment is appropriate only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In deciding a motion for summary judgment, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

"[A] moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001). To defeat summary judgment, the nonmoving party must then come forward with evidence sufficient to establish a genuine issue of material fact regarding that essential element. *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1363 (Fed. Cir. 2005).

### I. Obviousness

Under the Patent Act, "[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). Although the ultimate determination of obviousness under § 103 is a question of law, it is based

on several underlying factual findings, including (1) the scope and content of the prior art; (2) the level of ordinary skill in the pertinent art; (3) the differences between the claimed invention and the prior art; and (4) evidence of secondary factors, such as commercial success, long-felt need, and the failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

An invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Rather, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does," *id.*, although such a reason need not be explicitly stated in the prior art, *see id.* at 419. Furthermore, when there exists a finite number of identified, predictable solutions to a known problem, a combination that results in "anticipated success" is likely the product not of innovation, but of ordinary skill and common sense. *Id.* at 421.

Watson argues that it raised genuine issues of material fact regarding whether it would have been obvious to combine the Kovacs COC regimen with the administration of low-dose estrogen during the traditional hormone-free period to treat estrogen-withdrawal headaches in light of, *inter alia*, the Sulak articles and the '749 patent. Watson claims that the court, in granting summary judgment of nonobviousness, erred by, *inter alia*, (1) focusing on individual references instead of considering the teaching of the prior art as a whole; (2) improperly requiring clear and convincing evidence of invalidity on summary judgment; (3) ignoring all but three prior art references, including the 2000 Sulak article, as cumulative; (4) erroneously requiring that the prior art teach a

virtual guarantee, rather than a reasonable expectation, of success; and (5) failing to make a finding of the level of skill in the art.

Duramed responds that the district court correctly granted summary judgment of nonobviousness because Watson failed to present any evidence of a reason to combine Kovacs with 7 days of low-dose, unopposed estrogen to reduce the incidence of estrogen-withdrawal headache during the traditional hormone-free period. According to Duramed, by disclosing that headaches occurred throughout the menstrual cycle, the Kovacs article fails to suggest that the Kovacs regimen caused the headaches because of estrogen withdrawal. Rather, Duramed continues, the art taught that extended-cycle regimens were a cure for—not a cause of—such headaches, including the 2000 Sulak article, which discusses extended-cycle regimens and unopposed estrogen as *alternative* solutions to the problem of withdrawal headaches in traditional 28-day COC regimens. Regarding the '749 patent, Duramed claims that it also does not provide a motivation to modify Kovacs with unopposed estrogen because it does not associate estrogen-withdrawal headaches with any particular extended-cycle regime, let alone the extended-cycle Kovacs regimen. Finally, Duramed dismisses Watson's expert testimony as conclusory and thus insufficient to raise a genuine issue of fact.

Duramed also disagrees that the district court made any of the errors alleged by Watson. Rather, according to Duramed, the district court (1) correctly held Watson to the clear and convincing evidentiary standard on summary judgment; (2) implicitly made a finding on the level of skill in the art in Watson's favor; (3) correctly analyzed only three prior art references, rejecting the rest as cumulative; and (4) properly required Watson to show, not absolute certainty, but a reasonable expectation that

combining Kovacs with unopposed estrogen would succeed in reducing the incidence of estrogen-withdrawal headaches.

We agree with Watson that the district court erred in its obviousness analysis and, as a result, incorrectly granted summary judgment of nonobviousness. Specifically, the district court erred in assessing the content and scope of the prior art, leading it to incorrectly analyze each prior art reference in isolation without considering the prior arts' teaching as a whole in light of the creativity and common sense of a person of ordinary skill. The court also appears to have applied an incorrect evidentiary standard on summary judgment. Finally, the court failed to make any finding on the level of skill in the art. We address each in turn.

A. Content and Scope of the Prior Art

The district court erred in several of its findings on the disclosure of the Sulak articles and the '749 patent, which then infected the court's summary judgment decision. Regarding Sulak, the court rejected all consideration of the articles' teaching of the use of unopposed estrogen because that use was mentioned only as a "theoretical," rather than a tested, solution to estrogen-withdrawal headaches. *Duramed*, 701 F. Supp. 2d at 1169. A reference, however, is prior art for all that it discloses, and there is no requirement that a teaching in the prior art be scientifically tested, *see PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1363-64 (Fed. Cir. 2007), or even guarantee success, *see Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1295 (Fed. Cir. 2006), before providing a reason to combine. Rather, it is sufficient that one of ordinary skill in the art would perceive from the prior art a reasonable likelihood of success. *Id.*

Regarding the '749 patent, the district court first found that the patent "provides no reference or basis to a practitioner on the effects of adding unopposed estrogen to the end of an extended regimen in regards to hormone withdrawal headaches." *Duramed*, 701 F. Supp. 2d at 1170. The '749 patent, however, expressly teaches the administration of 7 days of 10 µg ethinyl estradiol during the traditional hormone-free period following a variety of extended-cycle COC regimens. '749 patent col.9 ll.48-52. Moreover, it teaches that the administration of unopposed estrogen is to reduce the "incidence of side effects, such as headaches within the framework of premenstrual syndrome." *Id.* The district court also found that the '749 patent discloses a variety of COC regimens and thus concluded that the patent "does not teach any one specific combination that would establish consistent knowledge in the community." *Duramed*, 701 F. Supp. 2d at 1170. However, the question is not whether there existed a consistent COC regimen in the art, but rather whether one of ordinary skill in the art would have been motivated to combine *the Kovacs regimen* with 7 days of low-dose, unopposed estrogen with the reasonable expectation that the addition of low-dose estrogen would successfully reduce the incidence of estrogen-withdrawal headaches during the hormone-free period.

Based on its errors in assessing the content of these prior art references, the district court improperly analyzed and rejected the teaching of each in isolation, concluding that each alone failed to establish by clear and convincing evidence a motivation to combine. Specifically, while recognizing that the Sulak articles identify headaches as a symptom of hormone withdrawal, the court ignored the articles' suggestion of unopposed estrogen as a possible solution, concluding instead that, because it remained an untested solution, "the Sulak article does not

show by clear and convincing evidence that a person of ordinary skill would have added unopposed estrogen to the traditional hormone-free interval to alleviate the hormone withdrawal symptoms that arise during that period." *Id.* at 1169-70. The district court next, as described above, rejected the disclosure of the '749 patent in its entirety, and thus failed to address its teaching of the use of unopposed estrogen to treat headaches following various extended-cycle COC regimens in light of the teaching of a specific extended-cycle COC regimen in Kovacs. *Id.* at 1170. Finally, the district court analyzed the Kovacs article without reference to the '749 patent or the Sulak articles, concluding that because the article taught that women on the regimen reported headaches "scattered throughout the [menstrual] cycle," and itself did not mention the use of unopposed estrogen, "the [Kovacs] article does not provide clear and convincing support" that a practitioner would treat headaches associated with the regimen by adding unopposed estrogen. *Id.* at 1169. Accordingly, the district court failed to properly consider the collective teaching of the prior art in light of the common sense and creativity of the person of ordinary skill in the art. *See KSR*, 550 U.S. at 419-21.

The district court also appears to have applied an incorrect evidentiary standard on summary judgment, incorrectly placing the burden of proof on the nonmoving party, Watson, to show clear and convincing evidence of invalidity as a matter of law. In this case, Duramed moved for summary judgment of nonobviousness, and thus the burden rested with Duramed to show that Watson had failed to come forth with clear and convincing evidence of an essential element of its *prima facie* case of obviousness. *See Eli Lilly*, 251 F.3d at 962. Although the ultimate evidentiary burden of showing clear and convincing evidence does not change on summary judgment,

Watson could defeat summary judgment by showing a genuine issue of material fact, which, if believed by the finder of fact, could provide clear and convincing evidence of a motivation to combine the prior art references. *See Freedman Seating*, 420 F.3d at 1364; *see also Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 881 (Fed. Cir. 1998) ("If facts remain in dispute, this court weighs the materiality of the dispute, i.e., whether resolution of the dispute one way or the other makes a difference to the final determination of obviousness."). That is the standard the district court should have made clear it was applying on summary judgment.

B. Level of Skill in the Art

A determination of obviousness requires a factual finding of the level of ordinary skill in the pertinent art, 35 U.S.C. § 103(a); *Graham*, 383 U.S. at 17, which the district court failed to make in this case. When a finding of the level of skill affects the court's ultimate conclusion under § 103, the failure to make such a finding constitutes reversible error. *See Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1574 (Fed. Cir. 1986), *overruled on other grounds by Knoff-Bremse Systeme v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004). The district court granted summary judgment of nonobviousness based on an unspecified level of skill, but a finding of a higher level of skill could have altered this ruling because, in general, an invention may be more obvious to one of higher skill than it might have been to one of lower skill. *See Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1573 (Fed. Cir. 1984).

Watson argues that the level of skill was high, requiring a medical degree and several years of experience in the field of reproductive endocrinology. Duramed argued below that even a nurse practitioner can be a person of

ordinary skill but suggests on appeal that the district court implicitly sided with Watson. There is no evidence for Duramed's contention. Rather, the district court appears to have simply rejected all of Watson's expert's testimony by finding that Thomas was not a person of ordinary skill, but extraordinary skill.[2] *See Duramed*, 701 F. Supp. 2d at 1170. That was error. Since a determination of obviousness is made from the vantage point of a legal construct, a hypothetical person having ordinary skill in the pertinent art, *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998), a person of extraordinary skill may opine on the knowledge of this hypothetical person, *see Moore v. Wesbar Corp.*, 701 F.2d 1247, 1253 (7th Cir. 1983) (holding that an expert of "more than the 'ordinary skill' required by the statute" was "well suited to assist the court in deciding what would be obvious to such a person"). Accordingly, Thomas's credentials as a tenured professor who actively participates in endocrinology research do not disqualify him from opining on what an ordinary person of lesser skill, whether a medical doctor with less research experience or a nurse practitioner, would have understood from the prior art.

Finally, contrary to Duramed's claim, Thomas's expert testimony was not merely conclusory. He connected each claim limitation with disclosures in the prior art, and his opinion on a motivation to combine rests on factual support in the record. J.A. 823-26, 836-38; *cf. Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1331 (Fed. Cir. 2009) (holding expert testimony insufficient to raise a genuine issue of fact when it relied on irrelevant prior art

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[2] The district court limited its discussion to the testimony of Thomas's prior use of the claimed extended-cycle COC regimen. Accordingly, it is unclear from the opinion whether or not the court credited other aspects of Thomas's testimony.

and failed entirely to address one claim limitation). Accordingly, this testimony should not have been disregarded on summary judgment. *See KSR*, 550 U.S. at 427 ("In considering summary judgment on th[e] question [of obviousness] the district court can and should take into account expert testimony, which may resolve or keep open certain questions of fact.").

In light of the errors made by the district court, we reverse the district court's grant of summary judgment of nonobviousness and remand. We note, however, that in reviewing the record *de novo* on summary judgment and crediting Duramed's lower level of skill in the art, the district court on remand may well conclude that the claimed extended-cycle COC regimen would have been obvious as a matter of law.

Kovacs teaches the claimed administration of 84 daily pills containing 150 µg levonorgestrel and 30 µg ethinyl estradiol. The '749 patent teaches the claimed administration of 10 µg ethinyl estradiol for 7 days during the traditional hormone-free period. Moreover, this administration follows a variety of extended-cycle COC regimens to treat estrogen-withdrawal headaches, which the 2000 Sulak article confirms for traditional 28-day COC regimens are "more common during the hormone-free intervals compared with the active-pill weeks." J.A. 1240-41. The 1997 Sulak article also teaches that women on extended-cycle COC regimens experience headaches during the hormone-free period.[3] J.A. 1225. And Watson's

[3] Watson stated at oral argument that the 1997 Sulak article tested the Kovacs regimen. Oral Arg. at 5:00-5:30. The article does list Kovacs in Table 1 as one prior art regimen, but it does not state that the women in its study were on the Kovacs regimen. Moreover, many of the women in the study did not stabilize on a regimen of

expert opined that one of skill in the art would have been motivated to combine the Kovacs COC regimen with the 7 days of unopposed estrogen taught by the '749 patent and the Sulak articles to arrive at the claimed invention because the Kovacs article recognized that the regimen resulted in headaches in some women, J.A. 824-25, although "scattered throughout the [menstrual] cycle," J.A. 229.

Thus, on the record before us, there appear to be no genuine issues of material fact that, based on the teaching of Kovacs, the '749 patent, and the Sulak articles, one of ordinary skill would have been motivated to combine the Kovacs regimen and 7 days of 10 µg unopposed ethinyl estradiol with a reasonable expectation that the combination would reduce the incidence of headaches associated with that regimen. Yet, Watson did not move for summary judgment of obviousness and stated at oral argument that it was "absolutely not" requesting that this court hold the asserted claims obvious as a matter of law. Oral Arg. at 1:12-1:43. In light of this procedural posture, Duramed did not have an opportunity to challenge Watson's *prima facie* case of obviousness or introduce any secondary considerations of nonobviousness. Accordingly, we leave that determination to the district court on remand.

## II. Exclusion of Testimony

A decision to exclude evidence raises an issue not unique to patent law, and thus we apply the law of the regional circuit in which the district court sits, in this case, the Ninth Circuit. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 382 F.3d 1367, 1370 (Fed. Cir. 2004). A district court's decision to exclude evidence is reviewed for abuse

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84 days of hormone-containing pills as claimed in the '969 patent. J.A. 1225

of discretion. *United States v. Pang*, 362 F.3d 1187, 1194 (9th Cir. 2004).

The district court excluded Thomas's testimony regarding his prior use of the claimed invention as uncorroborated in light of the "general rule" that "corroboration of oral testimony regarding prior invention or use is required before the evidence is admissible." *Duramed*, 701 F. Supp. 2d at 1166-67 (citing *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1217 (Fed. Cir. 2002), and *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1371 (Fed. Cir. 1998)). Watson does not argue that the testimony on prior use was in fact corroborated, but rather argues that because Thomas's testimony was not the sole evidence of obviousness, it should not have been excluded. Watson claims that although uncorroborated oral testimony alone is insufficient to meet the clear and convincing standard for invalidity, it may contribute to the clear and convincing evidence standard when not the sole evidence of invalidity.

Yet, Watson acknowledged that it was not relying on this testimony to support either its opposition to summary judgment or its *prima facie* case of obviousness. Oral Arg. at 22:25-23:35. We therefore decline to decide to what degree such evidence may or may not contribute to a determination of obviousness by clear and convincing evidence, concluding instead that Watson failed to meet its "particularly high hurdle" to demonstrate that the district court abused its discretion in excluding testimony on prior use. *Texas Digital*, 308 F.3d at 1218.

## CONCLUSION

For the foregoing reasons, we *reverse* the district court's grant of summary judgment of nonobviousness, *affirm* the court's exclusion of Watson's expert testimony on prior use, and *remand* for further proceedings consistent with this opinion.

**REVERSED IN PART, AFFIRMED IN PART, and REMANDED**

## COSTS

Costs to Watson.