NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

IMMUNOGEN, INC.,
Plaintiff-Appellant

v.

ANDREW HIRSHFELD, PERFORMING THE FUNCTIONS AND DUTIES OF THE UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Defendant-Appellee

2021-1939

Appeal from the United States District Court for the Eastern District of Virginia in No. 1:20-cv-00274-TSE-IDD, Judge T. S. Ellis, III.

Decided: March 25, 2022

MICHAEL E. JOFFRE, Sterne Kessler Goldstein & Fox, PLLC, Washington, DC, argued for plaintiff-appellant. Also represented by PAULINE PELLETIER, ERIC STEFFE.

DANIEL KAZHDAN, Office of the Solicitor, United States

Patent and Trademark Office, Alexandria, VA, argued for defendant-appellee. Also represented by MARY L. KELLY, THOMAS W. KRAUSE, FARHEENA YASMEEN RASHEED; MATTHEW JAMES MEZGER, RAJ PAREKH, Office of the United States Attorney for the Eastern District of Virginia, United States Department of Justice, Alexandria, VA.

Before NEWMAN, CLEVENGER, and STOLL, *Circuit Judges*.

CLEVENGER, *Circuit Judge*.

This case involves a civil action to obtain a patent under 35 U.S.C. § 145. Appellee ImmunoGen, Inc.'s ("ImmunoGen") U.S. Application No. 14/509,809 ("the '809 Application") describes methods of administering the immunoconjugate mirvetuximab for the treatment of cancer. After the Patent Trial and Appeal Board ("Board") of the United States Patent and Trademark Office ("USPTO") affirmed the examiner's rejection of the pending claims for obviousness and obviousness-type double patenting, ImmunoGen filed its § 145 suit in the Eastern District of Virginia.

The district court determined on summary judgment that the claims of the '809 Application are "fatally indefinite and fatally obvious" as a matter of law. *ImmunoGen, Inc. v. Iancu*, 523 F. Supp. 3d 773, 799 (E.D. Va. 2021). ImmunoGen appeals from the summary judgment. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

In its analysis, the district court resolved numerous factual disputes against non-movant ImmunoGen, an error that is fatal to its ultimate ruling. We therefore vacate the grant of summary judgment and remand for proceedings consistent with this opinion.

THE '809 APPLICATION

Immunoconjugates, such as mirvetuximab, are composed of an antibody coupled to a drug via a chemical

linker. The antibody portion allows the immunoconjugate to bind to a cell of interest, thereby permitting selective targeting of cancer cells for treatment. Mirvetuximab specifically targets Folate Receptor 1 ("FOLR1"), which is overexpressed in ovarian and peritoneal cancer cells.

Although mirvetuximab showed promise as a cancer treatment, Phase 1 clinical trials revealed it can have severe ocular side effects when administered at a dose of 7 mg per kg of the patient's total body weight ("TBW"). ImmunoGen determined that a dose of 6 mg per kg of the patient's adjusted ideal body weight ("AIBW") successfully maintains exposure of the drug at the therapeutically effective level while keeping it below the ocular toxicity threshold. It is undisputed that AIBW dosing had not previously been used for mirvetuximab, let alone any other immunoconjugate.[1]

ImmunoGen filed the '809 Application to claim this AIBW dosing method. Claim 1 is representative:

> 1. A method for treating a human patient having an FOLR1-expressing ovarian cancer or cancer of the peritoneum comprising administering to the patient an immunoconjugate which binds to FOLR1 polypeptide,
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> wherein the immunoconjugate comprises an antibody or antigen-binding fragment thereof that comprises the variable light chain (VL) complementarity determining region (CDR)-1, VL CDR-2, VL CDR-3, variable heavy chain (VH) CDR-1, VH CDR-2, and VH CDR-3 of SEQ ID NOs:

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[1] *See, e.g.*, J.A. 9916–17, 9919 (Resps. to Request for Admission ("RFA") Nos. 3 & 8–9); J.A. 10445 (Shah Dep. Tr. at 41:1–12); J.A.10655 (Tolcher Dep. Tr. at 55:4–19); J.A. 9992, 10043 (Figg Dep. Tr. at 36:7–21, 87:5–9).

> 6-9, 11, and 12,[2] respectively, and a maytansinoid, and
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> wherein the immunoconjugate is administered at a dose of 6 milligrams (mg) per kilogram (kg) of adjusted ideal body weight (AIBW) of the patient.

The '809 Application defines AIBW as "a size descriptor that accounts for sex, total body weight, and height." '809 Application at [0071]. It defines ideal body weight ("IBW"), which is used to calculate AIBW, as "a size descriptor that is unrelated to total body weight," as it is "an estimate of weight corrected for sex and height, and optionally frame size." *Id.* at [0069]. The application further discloses that IBW and AIBW "are discussed in more detail in Green and Duffull, *British Journal of Clinical Pharmacology* 58: 119-133 (2004)" ("Green"), which it incorporates by reference. *Id.* at [0072]. Green discloses several methods for calculating IBW and lists correction factors, each specific to a different drug, that can be used to adjust IBW to AIBW.

The AIBW and IBW definitions each includes a formula, introduced by the phrase "for example," for calculating the respective values. These "example" formulas are reproduced in Example 4, which relates to dosing IMGN853, i.e., mirvetuximab. As described in both the definitions and Example 4, AIBW is calculated as the patient's IBW plus 0.4 times their total (actual) body weight in kg minus their IBW. *Id.* at [0069], [0200]. For males, IBW is calculated as 0.9 times their height in centimeters minus 88; for females, IBW is calculated as 0.9 times their height in centimeters minus 92. *Id.* at [0071], [0200]. The equations are reproduced below:

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[2] The claimed "SEQ ID Nos" and other recited features identify the immunoconjugate as IMGN853, which is also known as mirvetuximab.

AIBW = IBW + 0.4(Actual weight in kg – IBW)
IBW (male) = 0.9H – 88
IBW (female) = 0.9H – 92

The '809 Application does not identify any other formulas for calculating AIBW or IBW. The "0.4" value in the AIBW formula is a specific correction factor for mirvetuximab, and is the only one presented in the '809 Application.

DISCUSSION

Summary judgment is appropriate when, drawing all justifiable inferences in favor of the non-moving party, there exists no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). We review a district court's summary judgment determination under the law of the regional circuit, *see Syngenta Crop Prot., LLC v. Willowood, LLC*, 944 F.3d 1344, 1355 (Fed. Cir. 2019), which, here, is the Fourth Circuit. "The Fourth Circuit reviews the grant of a motion for summary judgment de novo, viewing all evidence in the light most favorable to the non-moving party." *Id.* (citing cases).

Indefiniteness and obviousness are both issues of law that may rely on underlying factual findings, such as the knowledge, level, or understanding of those skilled in the art. *See BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017) (indefiniteness); *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1342 (Fed. Cir. 2015) (same); *Acorda Therapeutics, Inc. v. Roxane Lab'ys, Inc.*, 903 F.3d 1310, 1328 (Fed. Cir. 2018) (obviousness). Obviousness may also rely on factual findings regarding motivation to combine, reasonable expectation of success, and secondary considerations of nonobviousness. *Acorda*, 903 F.3d at 1328.

I

Although neither the examiner nor the Board rejected the claims of the '809 Application for indefiniteness, the USPTO (as permitted by statute) argued in the § 145 action that the term "AIBW" is indefinite. The district court agreed, concluding that the '809 Application fails to define IBW or AIBW in such a way that a skilled artisan would be informed, with reasonable certainty, as to the scope of the invention.[3] *ImmunoGen*, 523 F. Supp. 3d at 787, 799.

For support, the district court relies mainly on the definitions section of the '809 Application. In the district court's view, the "for example" language preceding the AIBW formula "makes clear that there are multiple ways to calculate AIBW," thereby "leav[ing] a skilled artisan to wonder or to guess whether the formula provided is the only one covered by the '809 Application." *Id.* at 787. This supposed uncertainty is compounded by the "for example" accompanying the IBW formula; the disclosure that IBW corrects "for sex and height, and ***optionally*** frame size"; and the incorporation of Green. *Id.* Although Example 4 of the '809 Application discloses dosing mirvetuximab using the same IBW and AIBW formulas provided in the definitions section, the district court declined to read Example 4 as "limit[ing] the scope of the claims." *Id.* at 788. The district court likewise declined to consider expert testimony as to whether a skilled artisan reviewing the '809 Application would understand which AIBW formula to use,

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[3] As dictated by the Supreme Court, "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). The district court applied this standard in its analysis. *See, e.g.*, *ImmunoGen*, 523 F. Supp. 3d at 786, 787.

characterizing the experts' disagreement as nothing more than an "attempt[] to create a factual dispute" in a situation where "[t]he undisputed, intrinsic evidence demonstrates that the term AIBW . . . is indefinite." *Id.*

Our review of the evidence, however, reveals that the underlying material factual findings are far from undisputed. For example, the district court found that the '809 Application "provides no limiting or defining guidance [to a skilled artisan] on the calculation of AIBW." *ImmunoGen*, 523 F. Supp. 3d at 787. Similarly, the district court found that the '809 Application discloses multiple formulas for calculating AIBW. *Id.* at 787–88. While the district court is correct that the definition section incorporates Green in its entirety and identifies the recited AIBW and IBW formulas as "example[s]," ImmunoGen identified other intrinsic evidence a skilled artisan would consider in determining the scope of the claims, including that: (1) the claims and specification are drawn to a specific dosing regimen for a specific immunoconjugate, which is significant in light of expert testimony that the correction factor used to calculate AIBW is drug-specific;[4] (2) Example 4 describes dosing mirvetuximab in accordance with the claimed method and uses the same AIBW and IBW formulas disclosed in the definitions section;[5] and (3) during the prosecution of the

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[4] *See, e.g.*, J.A. 9985–86, 10059 (Figg Dep. Tr. at 29:17–30:4, 103:2–6); J.A. 10225–26 (Figg Opening Rpt., ¶ 146); J.A. 10368–69, 10370 (Shah Reply Rpt., ¶¶ 11–12, 15).

[5] The district court incorrectly concluded that Example 4 plays no role in the indefiniteness inquiry. *See, e.g.*, *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1373 (Fed. Cir. 2014) ("We recognize that a patent which defines a claim phrase through examples may satisfy the definiteness requirement."); *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1336 (Fed. Cir. 2010) (holding that the

'809 Application, the USPTO never disputed the definiteness, or gave any indication it failed to understand the meaning, of the now-allegedly indefinite term.[6] ImmunoGen also presented extrinsic evidence regarding the knowledge of a skilled artisan. For instance, both parties' experts testified that AIBW dosing involves drug-specific formulas and correction factors.[7] This is confirmed by Green, which is incorporated into the '809 Application and identifies drug-specific correction factors for use in calculating AIBW.[8] When we view this evidence in the light most favorable to ImmunoGen—as we must in our review—we conclude that there are still disputed questions of material fact and summary judgment is therefore inappropriate.

II

The district court also held that the pending claims would have been obvious, concluding that the prior art taught every element of the pending claims, *ImmunoGen*, 523 F. Supp. 3d at 792–93; that a skilled artisan would have been motivated to use AIBW dosing to address the ocular toxicity problems associated with mirvetuximab with a reasonable expectation of success, *id.* at 793–95; and

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phrase "not interfering substantially" is sufficiently definite because a skilled artisan could use "the examples in the specification to determine whether interference with hybridization is substantial").

[6] *See, e.g.*, J.A. 11007 (Shah Opening Rpt., ¶¶ 197–200); J.A. 10369–70 (Shah Reply Rpt., ¶¶ 13–14); *see also* J.A. 10899–900.

[7] *See, e.g.*, J.A. 9985–86, 10059 (Figg Dep. Tr. at 29:17–30:4, 103:2–6); J.A. 10225–26 (Figg Opening Rpt., ¶¶ 144, 146); J.A. 10368–69 (Shah Reply Rpt., ¶¶ 11–12).

[8] J.A. 4445; *see also* J.A. 10225–26 (Figg Opening Rpt., ¶ 146).

that ImmunoGen's secondary considerations were unpersuasive, *id.* at 795–798.

In reaching this conclusion, the district court improperly resolved a number of factual findings against ImmunoGen. For example, the district court found that "ocular toxicity was a known negative effect of [immunoconjugates] like IMGN853." *Id.* at 793. But the expert testimony on which the district court relies does not directly support that statement. *See id.* at 793, n.40. Further, ImmunoGen presented evidence that (1) ocular toxicity is not well-understood;[9] (2) immunoconjugates have unique pharmacokinetic characteristics, making it difficult to generalize pharmacological effects;[10] (3) it was not known that mirvetuximab would cause ocular toxicity;[11] and (4) published results for Phase 1 testing of mirvetuximab reported no study drug-related serious adverse events or dose-limiting toxicity.[12] As another example, the district court concluded, based on statements made in International Published Application Nos. WO 2011/106528 ("Ab '528") and WO 2012/135675 ("Carrigan '675"), that "dosing of IMGN853 could 'easily' be determined." *ImmunoGen*, 523 F. Supp. 3d at 795 (quoting Carrigan '675); *see also id.* at 781 (quoting Ab '528). ImmunoGen's experts, however, testified that the contested statements relate to dosing in the context of treating patients, not in the context of determining a safe and effective dose in drug development, and that

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[9] *See, e.g.*, J.A. 10095–96 (Figg Dep. Tr. at 139:7–140:5); J.A. 11028 (Shah Opening Rpt., ¶ 235); J.A. 9595, 9597 (Tolcher Opening Rpt., ¶¶ 34, 39).

[10] *See, e.g.*, J.A. 9595 (Tolcher Opening Rpt., ¶ 34); J.A. 10980–81 (Shah Opening Rpt., ¶ 50).

[11] *See, e.g.*, J.A. 9995, 10021, 10024 (Figg Dep. Tr. at 39:6–14, 65:16–20, 68:13–22); J.A. 9941–45 (Resps. to RFA Nos. 64–74).

[12] *See, e.g.*, J.A. 9541.

determining a safe and effective dose for immunoconjugates is difficult.[13] Similarly, the district court found that switching "from 6 mg/kg of [TBW] dosing to 6 mg/kg AIBW dosing does not significantly change the dose for patients who are not significantly overweight or underweight," *id.* at 792–93, even though the '809 Application and other evidence show that this switch to AIBW dosing reduced adverse ocular events in Phase 1 clinical trials.[14]

For each of these examples, the district court erred in concluding that there is no disputed question of material fact. This error repeats across its other factual findings, including those relating to motivation to combine, reasonable expectation of success, and secondary considerations.

CONCLUSION

For the reasons stated above, we hold that the district court erred in granting summary judgment. We therefore vacate the district court's determination that the pending claims of the '809 Application are indefinite and would have been obvious, and remand for proceedings consistent with this opinion.

VACATED AND REMANDED

COSTS

No costs.

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[13] *See, e.g.*, J.A. 9612 (Tolcher Opening Rpt., ¶ 106); J.A. 10521–25 (Shah Dep. Tr. at 117:15–121:19); J.A. 10980–81 (Shah Opening Rpt., ¶ 50); J.A. 9595 (Tolcher Opening Rpt., ¶ 34).

[14] *See, e.g.*, '809 Application, Example 4; J.A. 11030–31 (Shah Opening Rpt., ¶ 239).