NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION, BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG,
Plaintiffs-Appellants

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC., MYLAN LABORATORIES LIMITED, AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC.,
Defendants-Appellees

2019-1172

Appeal from the United States District Court for the District of New Jersey in Nos. 3:15-cv-05982-PGS-TJB, 3:16-cv-00851-PGS-TJB, 3:16-cv-00852-PGS-TJB, 3:16-cv-01727-PGS-TJB, 3:16-cv-02394-PGS-TJB, Senior Judge Peter G. Sheridan.

Decided: March 16, 2020

LEORA BEN-AMI, Kirkland & Ellis LLP, New York, NY, argued for plaintiffs-appellants. Also represented by MIRA ATANASSOVA MULVANEY, JEANNA WACKER; LIZA M. WALSH, Walsh Pizzi O'Reilly Falanga LLP, Newark, NJ.

DEEPRO MUKERJEE, Katten Muchin Rosenman LLP, New York, NY, argued for all defendants-appellees. Defendants-appellees Mylan Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories Limited also represented by LANCE SODERSTROM; JOSEPH JANUSZ, Charlotte, NC; HOWARD ROBERT RUBIN, RAJESH RAM SRINIVASAN, ERIC THOMAS WERLINGER, Washington, DC; CHRISTOPHER L. MCARDLE, THOMAS J. PARKER, Alston & Bird LLP, New York, NY.

JEFFREY STEPHEN WARD, Green, Griffith & Borg-Breen LLP, Middleton, WI, for defendants-appellees Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc. Also represented by WENDY M. WARD; PAIGE STRADLEY, Merchant & Gould P.C., Minneapolis, MN.

Before DYK, MOORE, and HUGHES, *Circuit Judges*.

MOORE, *Circuit Judge*.

Appellants Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, Boehringer Ingelheim Corporation, and Boehringer Ingelheim Pharma GmgH & Co. KG (collectively, Boehringer) sued Mylan Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories, Ltd., Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, Appellees) for infringement of U.S. Patent Nos. 8,853,156, 9,173,859 and 8,673,927, which relate to the treatment of type 2 diabetes mellitus with DPP-IV inhibitors such as linagliptin. Appellees moved for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c) alleging that claims 10-17, 24 and 25 of the '156 patent are directed to ineligible

subject matter under 35 U.S.C. § 101. The district court granted Appellees' motion, holding the claims patent ineligible under the two-step framework of *Alice Corporation Pty. Ltd. v. CLS Bank International*. 573 U.S. 208, 217 (2014).

A bench trial ensued on the '859 and '927 patents. The district court held that claims 1, 14, 15, 20, and 21 of the '859 patent and claims 7, 9, 15, 17, 19, 25, and 26 of the '927 patent are invalid for obviousness-type double patenting in light of the claims of U.S. Patent No. 8,178,541, and invalid as obvious in view of U.S. Patent Application Publication No. 2004/0097510. Boehringer appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

For the reasons discussed below, we reverse the district court's judgment that claims 10–17, 24 and 25 of the '156 patent are directed to ineligible subject matter under 35 U.S.C. § 101 and remand for further proceedings. We affirm the district court's judgment that the asserted claims of the '859 and '927 patents are invalid for obviousness and obviousness-type double patenting.

DISCUSSION

I

The district court granted Appellees' motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c) holding claims 10–17, 24 and 25 of the '156 patent ineligible under § 101. The district court held that the claims are directed to an "abstract idea," namely "the act of administering the DPP-IV inhibitor to the targeted patient population." J.A. 108–09. The district court further determined that the claims fail to recite an inventive concept.[1]

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[1] The district court determined that "the additional features recited in claim 1 do not amount to 'significantly

We review a district court's Rule 12(c) dismissal for judgment on the pleadings under the law of the regional circuit. *Amdocs (Isr.) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1293 (Fed. Cir. 2016). The Third Circuit reviews a grant of judgment on the pleadings de novo. *Hanover Ins. Co. v. Urban Outfitters, Inc.*, 806 F.3d 761, 764 (3d Cir. 2015). In doing so, the Third Circuit views "the facts presented in the pleadings and the inferences to be drawn therefrom in the light most favorable to the nonmoving party." *Id.* (internal quotations omitted). Eligibility under § 101 is a question of law based on underlying facts that, ultimately, we review de novo. *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1166 (Fed. Cir. 2018).

In determining patent eligibility under § 101 "we first determine whether the claims at issue are 'directed to' a patent ineligible concept." *Natural Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1342 (Fed. Cir. 2019) (quoting *Alice Corp.*, 573 U.S. at 218). "As the Supreme Court has cautioned, we must be careful in this analysis as 'too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at

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more,' which transform the abstract idea of administering the DPP-IV inhibitor to a patent eligible subject matter." J.A. 111. As to claim 10, it declared that the additional features are "well-understood, routine, and conventional features that do not transform the abstract idea recited in claim 1 into a patent eligible subject matter." J.A. 114. Similarly, "the additional features recited in claims 11–17 do not add 'significantly more' to the abstract idea of claim 1" such that "claims 11–17 do not render claim 1 patent eligible under § 101." J.A. 115. Finally, as to claims 24 and 25, their additional features "do not add significantly more to the abstract idea of administering a DPP-IV inhibitor such that they transform the abstract idea into patent eligible subject matter." J.A. 116.

some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.'" *Id.* at 1342 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012)); *id.* at 1345 ("The fact that the human body responds to the treatment through biochemical processes does not convert the claim into an ineligible one."). We conclude claims 10–17, 24 and 25 of the '156 patent are directed to patent eligible subject matter.

The '156 patent relates to the treatment and/or prevention of metabolic diseases such as type 2 diabetes mellitus with DPP-IV inhibitors such as linagliptin "in patients for whom normal metformin therapy is not appropriate." '156 patent at 1:5–11. Type 2 diabetes may be associated with complications such as renal impairment or failure. *Id.* at 1:17–21. Because metformin is largely eliminated by the kidneys, "it is contraindicated in patients with renal disease or renal impairment." *Id.* at 1:62–65. The specification indicates that "it has now surprisingly been found that DPP-4 inhibitors as defined herein have surprising and particularly advantageous properties, which make them particularly suitable for treating and/or preventing . . . metabolic diseases, particularly diabetes . . . in patients for whom metformin therapy is inappropriate due to intolerability or contraindication against metformin . . . ." *Id.* at 9:30–39. It further explains, for example, that "[t]he DPP-4 inhibitor is substantially or mainly excreted via the liver . . . ." *Id.* at 13:45–46.

Claims 1 and 10 of the '156 patent recite:

> 1. A method of treating and/or preventing metabolic diseases in a patient for whom metformin therapy is inappropriate due to at least one contraindication against metformin comprising orally administering to the patient a DPP-IV inhibitor wherein the contraindication is selected from the group consisting of: renal disease, renal impairment or renal dysfunction, unstable or acute

> congestive heart failure, acute or chronic metabolic acidosis, and hereditary galactose intolerance.
>
> 10. The method according to claim 1 wherein the metabolic disorder is type 2 diabetes mellitus and wherein the contraindication is renal disease, renal impairment or renal dysfunction, and wherein said DPP-4 inhibitor is used for said patient in the same dose as for a patient with normal renal function.

Boehringer argues that the claims are directed to a "method of treating a specific disease ([type 2 diabetes mellitus]) for specific patients (with renal impairment) using a specific compound (linagliptin) at specific doses (same dose in patients with renal impairment as in patients with normal renal function) to achieve a specific outcome." Appellants' Br. 38. Appellees argue that the claims are directed to the natural law that "certain DPP-IV inhibitors (including linagliptin) are metabolized by the liver rather than the kidney." Appellees' Br. 38; *see also id.* at 43.

We hold that, consistent with this court's decision in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018), the claims are directed to a particular method of treatment under step one and are therefore patent eligible. The claims in *Vanda* involved a method of treating patients with schizophrenia that first required performing a genetic test to determine if a patient was a CYP2D6 poor metabolizer. *Id.* at 1121. Based on the results of that test, a particular dose of iloperidone was selected and internally administered. *Id.* As a result, the risk of QTc prolongation, a dangerous side effect, was decreased. *Id.* at 1121 & n.2. We held that the claims were not directed to a natural relationship between iloperidone, CYP2D6 metabolism, and QTc prolongation. *Id.* at 1134. While we acknowledged that the inventors had recognized the underlying relationships, we explained that those were not what was claimed. *Id.* at 1135. Instead, the claims were directed to a patent-eligible

method of using iloperidone to treat schizophrenia, "a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome." *Id.* at 1136; *see also Mayo*, 566 U.S. at 87 (distinguishing the *Mayo* claim from "a typical patent on a new drug or a new way of using an existing drug," because the *Mayo* claim did not "confine [its] reach to particular applications" of the natural laws relied upon).

The claims of the '156 patent are likewise directed to a method of treating type 2 diabetes mellitus using a DPP-IV inhibitor, such as linagliptin.[2] That "certain DPP-IV inhibitors (including linagliptin) are metabolized by the liver rather than the kidney," Appellees' Br. 38, "does not make the claim 'directed to' that natural ability." *Rapid Litigation Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1049 (Fed. Cir. 2016) (stating that the "natural ability of the subject matter to *undergo* the process does not make the claim 'directed to' that natural ability").

Because we hold that the claims are directed to a method of treatment at step one, we conclude the claims are patent eligible and need not reach step two. We do not, of course, at this stage address the issues of obviousness and obviousness-type double patenting with respect to these claims. Accordingly, we reverse the district court's grant of judgment on the pleadings and remand to the district court for further proceedings.

II

The district court held claims 1, 14, 15, 20, and 21 of the '859 patent and claims 7, 9, 15, 17, 19, 25, and 26 of the '927 patent (collectively, the claims at issue) invalid for obviousness-type double patenting and invalid as obvious in

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[2] We recognize that the district court made its decision in 2016 without the benefit of our decision in *Vanda* and its progeny, which dictate the conclusion we reach today.

view of the prior art. On appeal from a bench trial, we review a district court's conclusions of law de novo and its findings of fact for clear error. *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1358 (Fed. Cir. 2014). "A factual finding is clearly erroneous when, despite some supporting evidence, we are left with a definite and firm conviction that the district court was in error." *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1186 (Fed. Cir. 2014) (citing *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006)). "Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous." *Anderson v. City of Bessemer City*, 470 U.S. 564, 574 (1985) (citing *United States v. Yellow Cab Co.*, 338 U.S. 338, 342 (1949)). Obviousness is a question of law based on underlying facts, including the scope and content of the prior art. *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012). "As with statutory obviousness under 35 U.S.C. § 103, obviousness-type double patenting is an issue of law premised on underlying factual inquiries." *Eli Lilly and Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1376 (Fed. Cir. 2012).

The claims at issue relate to the treatment of type 2 diabetes mellitus with linagliptin in 2.5 or 5 mg doses. As to the '859 patent, claim 14 is illustrative:

> 14. An oral tablet formulation comprising 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in an amount of 2.5 mg or 5 mg optionally in combination with metformin, and a pharmaceutically acceptable carrier or diluent.

As to the '927 patent, claim 7, which depends from claim 1, is illustrative:

> 1. A method of treating type II diabetes mellitus comprising administering to a patient in need thereof a pharmaceutically effective oral amount of

> 1-[(4-methyl-quinazolin-2-yl)-methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, and a pharmaceutically effective amount of metformin, which is from 300 mg to 1000 mg once or twice a day, or delayed-release metformin in a dose of 500 mg to 1000 mg once or twice a day or 500 mg to 2000 mg once a day.
>
> 7. The method according to claim 1, wherein the 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine is administered in an oral dosage of 2.5 mg or 5 mg.

The district court held that the claims at issue are invalid for obviousness-type double patenting in light of the claims of Boehringer's earlier-expiring '541 patent. It also held that the claims would have been obvious in light of the '510 publication (the priority application with the same specification as the '541 patent). Boehringer argues that both of these conclusions depend on the district court's determination that the claimed dosages would have been obvious. The district court determined that because "the claimed invention's doses of linagliptin in 2.5 mg and 5 mg fall within the '510 publication[']s disclosed range of 1–100 mg," there is a presumption of obviousness. *See* J.A. 164 (citing *Tyco Healthcare Grp. LP v. Mutual Pharm. Co.*, 642 F.3d 1370, 1372–73 (Fed. Cir. 2011). The district court alternatively found that a person of ordinary skill in the art would have obtained the claimed dosages through routine experimentation. Because we conclude that the district court's alternative finding is not clearly erroneous, we need not decide whether the district court's presumption determination was correct.

In view of the evidence presented, the district court did not clearly err in determining that a skilled artisan would "have a reasonable expectation of arriving at the claimed 2.5 mg and 5 mg dosages" through routine

experimentation. J.A. 154; *see also* J.A. 164. For example, Dr. Grass testified that dose ranging studies are "conducted starting with a low dose, and sequentially moving through increasing doses." J.A. 147 (quoting J.A. 1037 at 720:6–9, *id.* at 720:10–721:10; *see also* J.A. 1158 at 1060:2–5 (Dr. Lam agreeing that "a person of ordinary skill in the art would understand the general guidelines that were issued by the FDA would include . . . dose-ranging studies"); J.A. 1259 at 1356:7–10 (Dr. Accili agreeing that dose-ranging studies are required for FDA approval). Dr. Grass further testified that linagliptin has a low IC_{50} value disclosed in the '510 publication indicating that it has a high potency. J.A. 1045 at 752:19–753:6 ("Using the '510 which we spoke about earlier, one would recognize that linagliptin is disclosed in the '510; it's a compound that's shown to have . . . the lowest IC_{50} value or the greatest potency; there's a preferred dose range of 1 to 100 milligrams; and there's a preferred list of compounds in which linagliptin is a member; one would be guided through that information of looking at the lowest end of the dose range for the most potent compound . . . ."). Additionally, one of the inventors of the '859 and '927 patents, Dr. Dugi, testified that "[r]egulators expect you to define the lowest maximum therapeutic dose," which may have the benefits of: (1) being a smaller, easier to swallow tablet; (2) being easier to formulate in combination pills; (3) having a lower risk of drug to drug interactions; and (4) reducing the risk of side effects. J.A. 1286 at 1464:11–17; J.A. 1289 at 1476:4–1477:16; J.A. 152–53. Finally, we see no clear error in the district court's secondary consideration analysis.

Accordingly, we affirm the district court's decision holding the asserted claims of the '859 and '927 patents invalid for obviousness and obviousness-type double patenting.

CONCLUSION

REVERSED-IN-PART, AFFIRMED-IN-PART, AND REMANDED

COSTS

Each party shall bear its own costs.