United States Court of Appeals for the Federal Circuit

ASTELLAS PHARMA, INC., ASTELLAS IRELAND CO., LTD., ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC.,
Plaintiffs-Appellants

v.

SANDOZ INC., ZYDUS PHARMACEUTICALS (USA) INC., ZYDUS LIFESCIENCES LTD., DBA ZYDUS CADILA, LUPIN LTD., LUPIN PHARMACEUTICALS, INC., LEK PHARMACEUTICALS, D.D.,
Defendants-Appellees

AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA LLC, ACTAVIS ELIZABETH LLC, PRINSTON PHARMACEUTICAL INC., ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., HUAHAI US INC., SOLCO HEALTHCARE U.S., LLC, WINDLAS HEALTHCARE PVT. LTD., WINDLAS BIOTECH LTD., TEVA PHARMACEUTICALS USA, INC.,
Defendants

2023-2032, 2023-2063, 2023-2089

Appeals from the United States District Court for the District of Delaware in Nos. 1:20-cv-01589-JFB-CJB, 1:21-cv-00425-JFB-CJB, 1:21-cv-00664-JFB-CJB, Senior Judge Joseph F. Bataillon.

Decided: September 18, 2024

PAUL WHITFIELD HUGHES, III, McDermott Will & Emery LLP, Washington, DC, argued for plaintiffs-appellants. Also represented by ANDREW LYONS-BERG, CHARLES H. SEIDELL; JASON ALBERT LEONARD, SIMON ROBERTS, New York, NY; DANIEL M. SILVER, McCarter & English, LLP, Wilmington, DE.

WILLIAM R. ZIMMERMAN, Knobbe, Martens, Olson & Bear, LLP, Washington, DC, argued for all defendants-appellees. Defendants-appellees Lupin Ltd., Lupin Pharmaceuticals, Inc. also represented by ANDREA L. CHEEK; CAROL PITZEL CRUZ, Seattle, WA.

KEVIN PATRICK BURKE, Rakoczy Molino Mazzochi Siwik LLP, Chicago, IL, for defendants-appellees Sandoz Inc., Lek Pharmaceuticals, d.d. Also represented by DEANNE M. MAZZOCHI, WILLIAM A. RAKOCZY, RACHEL PERNIC WALDRON.

MICHAEL GAERTNER, Locke Lord LLP, Chicago, IL, for defendants-appellees Zydus Pharmaceuticals (USA) Inc., Zydus Lifesciences Ltd. Also represented by DAVID BRIAN ABRAMOWITZ, HUGH S. BALSAM, CAROLYN ANNE BLESSING, EMILY SAVAS, JONATHAN B. TURPIN.

Before LOURIE, PROST, and REYNA, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Astellas Pharma, Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, "Astellas") appeal from the final judgment of the United States District Court for the District of Delaware.

Following a five-day bench trial on issues of infringement and validity under 35 U.S.C. § 112, the district court determined, *sua sponte*, that claims 5, 20, and 25 of U.S. Patent 10,842,780 ("the '780 patent") are invalid under 35 U.S.C. § 101 as directed to an ineligible natural law. *Astellas Pharma Inc. v. Sandoz Inc.*, No. 20-cv-1589, 2023 WL 3934386 (D. Del. June 9, 2023) ("*Decision*"). For the reasons set forth below, we vacate the judgment and remand.

BACKGROUND

I

In 2012, the U.S. Food and Drug Administration ("FDA") approved the New Drug Application ("NDA") for extended-release mirabegron tablets for the treatment of overactive bladder ("OAB"), which Astellas markets and sells under the brand name Myrbetriq®. Mirabegron is a beta-3 agonist that stimulates beta receptors in the bladder, thereby inducing bladder relaxation and improving bladder function.

During the development of Myrbetriq, Astellas discovered that immediate-release formulations of mirabegron exhibit an undesirable "food effect," meaning that the bioavailability of the drug is affected by the presence or absence of food in a patient's stomach. Astellas observed that when patients took the drug with a meal, the levels of mirabegron that were absorbed into the blood were too low to impart any therapeutic benefit. But when patients took the drug on an empty stomach, mirabegron was absorbed too rapidly, reaching potentially toxic concentrations in the blood. To solve this problem, Astellas developed sustained-release formulations of mirabegron, which abated the undesirable food effect. Those formulations are covered by the claims of the '780 patent.

The '780 patent contains two independent claims, each of which is directed to a sustained-release pharmaceutical composition comprising mirabegron. Independent claim 1,

from which asserted claims 5 and 20 ultimately depend, recites:

> 1. A pharmaceutical composition, comprising 10 mg to 200 mg of [mirabegron], or a pharmaceutically acceptable salt thereof, in a sustained release hydrogel-forming formulation comprising a hydrogel-forming polymer having an average molecular weight of 100,000 to 8,000,000 and an additive having a water solubility of at least 0.1 g/mL at 20±5° C.,
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> wherein the hydrogel-forming polymer is at least one compound selected from the group consisting of polyethylene oxide, hydroxypropyl methylcellulose, hydroxypropyl cellulose, carboxymethyl cellulose sodium, hydroxyethyl cellulose, and a carboxyvinyl polymer,
>
> wherein the additive is at least one selected from the group consisting of polyethylene glycol, polyvinylpyrrolidone, D-mannitol, D-sorbitol, xylitol, lactose, sucrose, anhydrous maltose, D-fructose, dextran, glucose, polyoxyethylene hydrogenated castor oil, polyoxyethylene polyoxypropylene glycol, polyoxyethylene sorbitan higher fatty acid ester, sodium chloride, magnesium chloride, citric acid, tartaric acid, glycine, ß-alanine, lysine hydrochloride, and meglumine, and
>
> wherein a drug dissolution rate from the pharmaceutical composition is 39% or less after 1.5 hours, and at least 75% after 7 hours, as measured in accordance with United States Pharmacopoeia in 900 mL of a USP buffer having a pH of 6.8 at a paddle rotation speed of 200 rpm.

'780 patent at col. 20, ll. 19–47; J.A. 8617–18 (Certificate of Correction). Asserted claim 5, which depends directly from claim 1, recites:

> 5. The pharmaceutical composition according to claim 1, wherein the hydrogel-forming polymer is at least one compound selected from the group consisting of polyethylene oxide, hyd[r]oxypropyl methylcellulose, and hydroxypropyl cellulose.

'780 patent at col. 20, ll. 61–65; J.A. 8617–18 (Certificate of Correction). Asserted claim 20, which depends from claim 1 by way of claims 16 and 18, recites:

> 20. A method for treating overactive bladder comprising administering the tablet according to claim 18 to a subject in need thereof.

'780 patent at col. 22, ll. 6–8. Claim 18 recites "[a] tablet, comprising the pharmaceutical composition according to claim 16," *id.* at col. 22, ll. 1–2, and claim 16 recites "[t]he pharmaceutical composition according to claim 1, comprising 10 mg to 200 mg of [mirabegron]," *id.* at col. 21, ll. 30–33.

Independent claim 22, from which asserted claim 25 ultimately depends, recites:

> 22. A pharmaceutical composition, comprising 10 mg to 200 mg of [mirabegron], or a pharmaceutically acceptable salt thereof, in a sustained release hydrogel-forming formulation comprising a means for forming a hydrogel and a means for ensuring penetration of water into the pharmaceutical composition,
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> wherein a drug dissolution rate from the pharmaceutical composition is 39% or less after 1.5 hours, and at least 75% after 7 hours, as measured in accordance with United States Pharmacopoeia in 900 mL of a USP buffer having a pH of 6.8 at a paddle rotation speed of 200 rpm.

Id. at col. 22, ll. 13–25. Asserted claim 25, which depends from independent claim 22 by way of claim 23, recites:

> 25. A tablet, comprising the pharmaceutical composition according to claim 23.

Id. at col. 22, ll. 32–33. Claim 23 recites "[t]he pharmaceutical composition according to claim 22, comprising 10 mg to 200 mg of [mirabegron]." *Id.* at col. 22, ll. 26–29.

In short, asserted claims 5, 20, and 25 are generally directed to a pharmaceutical composition comprising mirabegron, a method of treating OAB using that composition, and a tablet comprising that composition, respectively.

II

On November 24, 2020, the day that the '780 patent issued, Astellas sued each of Sandoz Inc., Zydus Pharmaceuticals (USA) Inc., Zydus Lifesciences Ltd., dba Zydus Ca-Dila, Lupin Ltd., Lupin Pharmaceuticals, Inc., and Lek Pharmaceuticals, D.D. (collectively, "Sandoz") for patent infringement under 35 U.S.C. § 271(e)(2)(A) based on the Abbreviated New Drug Application ("ANDA") each had submitted in 2016, seeking FDA approval to market and sell generic versions of Myrbetriq.[1] The cases were consolidated and proceeded to discovery.

On July 7, 2021, Sandoz produced its initial invalidity contentions. *See* J.A. 651–52. In those contentions, Sandoz claimed that the asserted claims were invalid under each of 35 U.S.C. §§ 102 (for anticipation), 103 (for obviousness), and 112 (for each of written description, enablement, and indefiniteness). Astellas Br. 11–12. Over a year later, on August 29, 2022, Sandoz produced its final invalidity contentions, maintaining each of those same grounds of

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[1] Astellas previously sued Sandoz in 2016 for infringement of certain then-listed Orange Book patents. *E.g.*, *Astellas Pharma Inc. v. Sandoz Inc.*, No. 16-cv-952 (D. Del. filed Oct. 14, 2016). But the parties thereafter reached a settlement, and those cases were dismissed.

invalidity. *Id.* at 12; J.A. 1501–02. Sandoz did not pursue an invalidity defense under 35 U.S.C. § 101 during the discovery phase of the litigation.

Nearing the February 6, 2023 trial date, the parties continued to narrow their theories of the case. In mid-January, the parties filed a joint proposed pre-trial order, in which Sandoz agreed to limit its invalidity defenses to obviousness under 35 U.S.C. § 103 and each of written description, enablement, and indefiniteness under § 112. *See generally* J.A. 6505–36 (Sandoz's Statement of Issues of Law that Remain to be Litigated). Then, on February 1, 2023, the parties filed a joint stipulation in which Astellas agreed to assert only claims 5, 20, and 25 of the '780 patent, while Sandoz agreed to limit its invalidity defenses to only those arising under § 112. J.A. 6591–93. Accordingly, in the days leading up to trial, Sandoz waived any challenge to the asserted claims arising under §§ 102 and 103. The five-day bench trial came and went with no discussion, let alone argument, from the parties as to the patent eligibility of the asserted claims. Nor did that issue arise in the parties' post-trial briefing.

Nevertheless, the district court issued a final decision holding asserted claims 5, 20, and 25 of the '780 patent invalid as directed to patent-ineligible subject matter under 35 U.S.C. § 101. *Decision* at *2. Relying on Astellas's statement in its post-trial briefing, that, in the context of enablement under § 112, the "inventive concept of the '780 Patent was discovering the dissolution rate that would address the food effect and achieving it using previously known formulation technology," *id.* (quoting Astellas's post-trial rebuttal brief, J.A. 7416) (emphases omitted), the district court determined that "Astellas concedes that the '780 patent is enabled because it claims invalid subject matter: a natural law applied via routine, conventional, and well-known methods." *Id.* (citing *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66 (2012)). Thus, because the claimed invention "reflects merely the

discovery of the food-effect-resolving dissolution profile," the district court deemed the asserted claims invalid as patent ineligible. *Id.* at *1.

Following the entry of judgment, Sandoz, the prevailing party, moved pursuant to Federal Rule of Civil Procedure 52(b) for the district court to make additional findings of fact and conclusions of law on the issues actually presented at trial—namely, infringement and validity under § 112. J.A. 8507–11. In that motion, Sandoz argued that it anticipated that Astellas would appeal the judgment and argue that "a § 101 defense [] was not presented at trial or in the post-trial briefing" and that the defense "is currently not set forth in the [c]ourt's opinion in terms of the claim language itself." *Id.* at 8508–09 (citing *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1149 (Fed. Cir. 2016), for the proposition that a § 101 inquiry must be based on the language of the claims themselves). The district court denied that motion, concluding that, despite Sandoz's concerns, "[t]he [c]ourt could not have better invoked [*Mayo*]." *Astellas Pharma Inc. v. Sandoz Inc.*, No. 20-cv-1589 (D. Del. June 27, 2023), ECF 577, J.A. 8512–14 ("*Rule 52(b) Decision*").

Astellas timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I

The Supreme Court has made clear that, "[i]n our adversary system, in both civil and criminal cases, in the first instance and on appeal, we follow the principle of party presentation. That is, we rely on the parties to frame the issues for decision and assign to courts the role of neutral arbiter of matters the parties present." *Greenlaw v. United States*, 554 U.S. 237, 243 (2008). By rendering its decision on a ground not raised by any party at any stage of the proceedings, and by expressly declaring that it "sits not [as] an

arbiter to resolve the disputes on the parties' favored terrain," *Decision* at *2, the district court disregarded the longstanding principle of party presentation and, in doing so, abused its discretion. *United States v. Sineneng-Smith*, 590 U.S. 371, 375 (2020) (providing that departures from the principle of party presentation are reviewed for abuse of discretion); *United States v. Dowdell*, 70 F.4th 134, 146 (3d Cir. 2023) (same); *see Innogenetics, N.V. v. Abbott Lab'ys*, 512 F.3d 1363, 1371 (Fed. Cir. 2008) ("We review procedural issues not unique to patent law under regional circuit law.").

To be sure, "[t]he party presentation principle is supple, not ironclad," and there are circumstances in which it may be appropriate for a court to take a "modest initiating role" in the shape of the litigation. *Sineneng-Smith*, 590 U.S. at 376. But rendering a patent invalid on a basis not advanced by any party is not such a circumstance.

One cornerstone of patent litigation lies in 35 U.S.C. § 282, which provides that "[a] patent shall be presumed valid" and that "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." That statutory prescription mandates that the party asserting an invalidity defense must prove that defense by clear and convincing evidence. *Microsoft Corp. v. I4I Ltd. P'ship*, 564 U.S. 91, 95 (2011). It thus follows that, in a court proceeding, a patent is not found "valid." *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1569 (Fed. Cir. 1987) ("It is neither necessary nor appropriate for a court to declare a patent valid.") (citing *Env't Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 699 n.9 (Fed. Cir. 1984)). Rather, when a patent owner prevails in the face of an invalidity defense or counterclaim, it merely means that the patent challenger has failed to carry its burden of establishing, in that particular case, invalidity by clear and convincing evidence. *See id.* at 1569–70; *accord Shelcore, Inc. v. Durham Indus., Inc.*, 745 F.2d 621, 627 (Fed. Cir. 1984) ("A patent is not held

valid for all purposes but, rather, not invalid on the record before the court."). By statute then, the court's role in issues of patentability is straightforward. It "does not require [the court] to conclude whether something was or was not 'invented', or whether the court subjectively considers the invention 'worthy' of patent protection." *Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1457 n.1 (Fed. Cir. 1984). Rather, the court's role is simply "to determine whether the patent's challenger carried the burden of establishing invalidity." *Id.*

Here, the district court appears to have misapprehended its role in adjudicating the issue of patentability. It interpreted Astellas's "zealous defense" on issues of § 112 as "conced[ing] that the '780 patent is enabled because it claims invalid subject matter: a natural law applied via routine, conventional, and well-known methods." *Decision* at *1. It then used that "concession" to hold the patent invalid on a ground never advanced by Sandoz. That was an abuse of discretion. Curiously, the district court did appear to appreciate that the issue of patent eligibility was not asserted by Sandoz. In its denial of Sandoz's Rule 52(b) motion, the court acknowledged Sandoz's "worry [that] the parties inadequately raised the matter of subject-matter eligibility at trial or in briefing." *Rule 52(b) Decision*, J.A. 8512. But it deemed that worry unwarranted because of the "fundamental flaw" it sensed "in the [parties'] assertion that patent litigants may, in essence, consent around the bounds of patent eligibility." *Id.* And therein lies the problem. It is for the *parties*—not the court—to chart the course of the litigation. *See Lannom Mfg. Co. v. U.S. Int'l Trade Comm'n*, 799 F.2d 1572, 1579 (Fed. Cir. 1986) ("It is beyond cavil that a district court does not have authority to invalidate a patent at its own initiative if validity is not challenged by a party.").

Further, the district court's treatment of patent eligibility suffered from its own "fundamental flaw." It appears

that the district court believed patent eligibility under 35 U.S.C. § 101 to be a threshold inquiry that it had a duty to address—even in the silence of the parties—akin to, for example, subject-matter jurisdiction. But the presumption of validity afforded to patents under § 282 applies equally to *all* grounds of validity, including the eligibility of the claimed subject-matter. *Cellspin Soft, Inc. v. Fitbit, Inc.*, 927 F.3d 1306, 1319 (Fed. Cir. 2019) ("Th[e] presumption reflects the fact that the Patent and Trademark Office has already examined whether the patent satisfies 'the prerequisites for issuance of a patent,' including § 101." (quoting *Microsoft*, 564 U.S. at 95–96)).[2] Accordingly, to the extent the district court believed that validity under § 101 is treated any differently than validity under §§ 102, 103, and 112 for purposes of the party presentation principle, that was error.

Sandoz's attempts to excuse the district court's departure from that principle are unavailing. In its view, the district court acted within its authority in light of precedent and Astellas's "stunning admissions" at trial regarding the invention. Sandoz Br. 23. Relying on cases from the late 1800s and certain non-binding out-of-circuit cases,[3] Sandoz argues that "[t]he Supreme Court has long

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[2] To be sure, § 101 is a threshold inquiry in *obtaining* patent protection. *See In re Comiskey*, 554 F.3d 967, 973 (Fed. Cir. 2009) (explaining, in the context of patent prosecution, that "[o]nly if the requirements of § 101 are satisfied is the inventor allowed to pass through to the other requirements for patentability, such as novelty under § 102 and . . . non-obviousness under § 103" (internal quotation marks and citation omitted)).

[3] Sandoz also relies on *Comiskey* for the proposition that the Federal Circuit has "considered § 101 issues without prompting from the parties." Sandoz Br. 20–21. *Comiskey* was an appeal from a decision of the Board of

held that a court may consider the eligibility or validity of a patent, even if such a defense is not raised by the defendant in the action." *Id.* at 18 (citing *Slawson v. Grand Street, P.P & F.R. Co.*, 107 U.S. 649, 652 (1883); *Brown v. Piper*, 91 U.S. 37, 43–44 (1875); *Dunbar v. Myers*, 94 U.S. 187, 188 (1876)); *see id.* at 19–20 (citing *Barkeij v. Lockheed Aircraft Corp.*, 210 F.2d 1, 1 (9th Cir. 1954); *Howes v. Great Lakes Press Corp.*, 679 F.2d 1023, 1028 (2d Cir. 1982)). But those decisions were rendered before, or did not address the impact of, the Patent Act of 1952's codification of a patent's presumption of validity and the requirement that a patent challenger affirmatively plead its defenses. *See* Pub. L. No. 82-593, § 282, 66 Stat. 792, 812 (1952) (codified at 35 U.S.C. § 282). We therefore find Sandoz's reliance on those cases unpersuasive.[4]

Patent Appeals and Interferences ("Board"), determining that a patent application was unpatentable under § 103. 554 F.3d at 969. We affirmed the Board's judgment of unpatentability under § 101. *Id.* While neither the examiner nor the Board had made a patentability determination under § 101, we confirmed that both the APA and the Supreme Court's decision in *SEC v. Chenery Corp.*, 318 U.S. 80 (1943), "made clear that a reviewing court can (and should) affirm *an agency decision* on a legal ground not relied on by *the agency* if there is no issue of fact, policy, or agency expertise." *Id.* at 974 (emphases added). The APA and *Chenery* principles that existed in *Comiskey* do not exist in the present case.

[4] For the first time at oral argument, Sandoz argued that it did plead an invalidity defense under § 101, referencing each Defendant-Appellee's answer to Astellas's complaint. *See* Oral Arg. at 16:42–57, *available at* https://oralarguments.cafc.uscourts.gov/default.aspx?fl=23-2032_08072024.mp3 (counsel for Sandoz arguing that "[t]he answers contain affirmative defenses under § 101,

Sandoz's invocation of public policy to justify the district court's decision is no more persuasive. Sandoz Br. 23–24 (arguing that the "public has a strong interest in the elimination of invalid pharmaceutical patents that delay or deter low-cost generic alternatives"). That argument is entirely irrelevant to the scope of a court's authority to stray from the case as designed by the parties. Indeed, we have long rejected such "public responsibility" concerns in favor of adherence to the party presentation principle. *See Lannom Mfg.*, 799 F.2d at 1579 (rejecting argument that the International Trade Commission has a public responsibility to "verify the validity of any patent brought before it").

Accordingly, because the district court abused its discretion in holding the asserted claims invalid under 35 U.S.C. § 101, a ground not invoked by Sandoz, we vacate the judgment and remand for adjudication of the issues properly raised and adequately supported by the record. Those issues are limited to infringement and validity under 35 U.S.C. § 112. *See* J.A. 6591–93.

II

We turn now to Astellas's request that this case be reassigned to a different district court judge on remand. Astellas argues that "[t]aken together, the district court's two post-trial decisions are rather extraordinary," Astellas Br. 55, such that reassignment is necessary to maintain an appearance of impartiality and fairness in the forthcoming remand proceedings.

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and Lupin's [counterclaim] has an express statement under § 101"). Sandoz did not raise that argument anywhere on appeal. Thus, it is forfeited. *See Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 800 (Fed. Cir. 1990) (noting we have discretion to consider arguments not raised in a party's appellate brief).

Reassignment is "an exceptional remedy, one that we weigh seriously and order sparingly." *United States v. Kennedy*, 682 F.3d 244, 258 (3d Cir. 2012); *see Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc.*, 714 F.3d 1289, 1298 (Fed. Cir. 2013) (providing that reassignment requests are evaluated "under the law of the regional circuit in which the district court sits"). When reviewing requests for reassignment, the Third Circuit applies "a standard that calls for reassignment when a reasonable person, with knowledge of all the facts, would conclude that the judge's impartiality might reasonably be questioned." *Arrowpoint Cap. Corp. v. Arrowpoint Asset Mgmt., LLC*, 793 F.3d 313, 329 (3d Cir. 2015) (internal quotation marks and citations omitted). Having considered the parties' arguments and having undertaken our own review of the district court proceedings, we decline to order the extraordinary remedy of reassignment in this case.

Astellas first argues that the district court's failure to abide by the party presentation principle is, "standing alone," enough to warrant reassignment. *See* Astellas Br. 55–56. We disagree. The Third Circuit has made clear that "adverse rulings—even if they are erroneous—are not in themselves proof of prejudice or bias" that warrant judicial reassignment. *Arrowpoint*, 793 F.3d at 330. We have already concluded that the district court abused its discretion, as a matter of procedure, in rendering its judgment. And, although we have serious doubts that, on the merits, the asserted claims—directed to nonnatural compositions of matter and associated methods of use—are ineligible for patent protection (an issue we decline to resolve), those kinds of errors, *i.e.*, errors relating to the propriety of the district court's analysis, are insufficient to warrant reassignment.

Astellas next points to various statements that the district court made in its two decisions on appeal as evidencing judicial bias. For example, in its denial of Sandoz's Rule 52(b) motion, the district court stated that "[t]he

pharmaceutical industry, to put it mildly, has perverted th[e] intent [of the Hatch-Waxman Amendments]. With alarming regularity since, brand and generic drug manufacturers have colluded to protect weak or invalid patents and share in the startling profits." *Rule 52(b) Decision*, J.A. 8513 (citing an unrelated antitrust litigation concerning the sale of a type 2 diabetes drug). The district court further stated that this "case is about the pharmaceutical industry's long-standing 'innovation' of patenting extended-release formulas for soon-to-expire active-ingredient patents," a practice the district court believes the U.S. Patent and Trademark Office has "accommodated" by issuing patents to such inventions. *Id.*

We agree with Astellas that these statements have no relevance to the proceedings in *this* case, which are limited to the issues of infringement and validity under 35 U.S.C. § 112 of three claims of the '780 patent. We further understand Astellas's concern that the district court's commentary may evidence a personal frustration with the pharmaceutical industry as a whole. *See also* Sandoz Br. 43 ("And to the extent that the district court's opinions expressed a frustration with the pharmaceutical industry, both 'brand and generic manufacturers' were mentioned."). To be sure, these proceedings are not an appropriate venue for those frustrations to be aired, let alone acted upon. *See Sineneng-Smith*, 590 U.S. at 376 ("[Courts] do not, or should not, sally forth each day looking for wrongs to right." (internal quotation marks and citation omitted)).

Although we have concerns with the analysis of the district court, we are not convinced that the judge, who has overseen nearly two hundred patent cases and has ruled in favor of both innovative and generic manufacturers alike, cannot resolve the outstanding issues impartially and fairly, particularly now that we have clarified the proper course for adjudication. Significantly, other than the court's two rulings, Astellas cannot identify any instance in the life of this nearly four-year-old litigation in which

the district court judge acted in a way that called into question his ability to do just that. Further, as Sandoz points out, the district court judge is currently presiding over two related cases that concern the same or similar validity issues on similar subject matter. *See* Sandoz Br. 48 n.6.

Ultimately, we trust that, upon remand, the district court can and will take an objective, measured, and thorough look into the legal issues and evidence of record to resolve only those disputes that exist between the parties.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the reasons set forth above, we vacate the district court's judgment and remand for adjudication of the case as it was shaped by the parties.

VACATED AND REMANDED

COSTS

No costs.