No.

In the Supreme Court of the United States

ALLERGAN SALES, LLC,

Petitioner,

v.

SANDOZ, INC., ALCON LABORATORIES, INC., ALCON RESEARCH, LTD.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the Federal Circuit may ignore a factual stipulation, contrary to this Court's precedent, and decisions of numerous circuit courts, holding that factual stipulations are binding?

2. Whether the Federal Circuit's finding of non-infringement by ignoring a factual stipulation should, at a minimum, be vacated because it did not mention the stipulation or address Allergan's arguments that the stipulation was binding, even though it was Allergan's lead argument on appeal?

RULES 14.1(b) AND 29.6 STATEMENT

All parties are identified in the caption of this petition.

Petitioner Allergan Sales, LLC is an indirect subsidiary of Allergan plc.

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PETITION FOR A WRIT OF CERTIORARI

Allergan Sales, LLC respectfully petitions for a writ of *certiorari* to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The court of appeals issued a non-precedential opinion, (App., *infra*, 1a-10a), as reported at 717 Fed. App'x 991 (Fed. Cir. 2017), and denied rehearing (App. 182a-183a). The district court's relevant opinions, (App. 11a-181a), are not reported in F. Supp. 2d, and the two of them are not reported on Westlaw either. The claim construction opinion is available at 2016 WL 1224868 (E.D. Tex. Mar. 29, 2016).

JURISDICTION

The court of appeals entered its judgment denying rehearing on March 28, 2018. This Court extended the time to file this petition to June 29, 2018. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

35 U.S.C. § 271(e)(2) provides in pertinent part:

> It shall be an act of infringement to submit—
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent. . . .

INTRODUCTION

Stipulations of fact play a critical role in federal court litigation. Through them, the parties narrow the issues for decision, thereby saving the judiciary's resources to litigate the issues that truly matter. This case presents an important issue regarding the enforceability of factual stipulations where the Federal Circuit has departed from the law of this Court and every other circuit.

In a prior case, Sandoz stipulated that its proposed generic drug product infringed Allergan's U.S. Patents 7,030,149 and 7,320,976, which cover Allergan's sight-saving COMBIGAN® product that is FDA approved to treat glaucoma and ocular hypertension. The stipulation provided that it was applicable "in any future proceeding relating to the subject matter of the present litigation." After losing the first litigation on infringement and validity, Sandoz made a minor amendment to its generic drug application, forcing Allergan to file this second patent infringement suit to protect its inventions. Sandoz's amendments did not change the composition of its product or the ingredients used. And the amendments were not material to the non-infringement argument Sandoz prevailed on in this case. Instead, the district court found that the amendments' "only utility" was "as a key to open the door to arguments that Sandoz regretted giving up in" the prior litigation. Nevertheless, the district court allowed Sandoz to make the arguments (without discussing if the stipulation was binding) and, ultimately, the Federal Circuit found non-infringement of the same patents that Sandoz had previously stipulated to infringing (along with an additional patent). In its opinion, the Federal Circuit never once mentioned the stipulation, even though it was Allergan's lead infringement argument on appeal.

This Court should intervene and enforce the stipulation or, at a minimum, remand with instructions for the Federal Circuit to address the issue. The stipulation is plainly enforceable under black letter law. To allow parties to renege on stipulations, as Sandoz did, is unfair to parties who relied on those stipulations; wastes judicial resources; and has profound consequences for future cases, as almost every case involves a stipulation of some sort. Further, the Federal Circuit's failure even to mention the issue erodes public confidence in the integrity of judicial decision-making and will severely impact the willingness of parties to enter stipulations of fact in future cases.

STATEMENT OF THE CASE

I. Sandoz Stipulates to Patent Infringement in the Parties' First Litigation.

Glaucoma is an incurable disease of the eye that gradually robs patients of their vision and can eventually lead to blindness. It is caused by elevated pressure, known as intraocular pressure (IOP), in the eye. When IOP is elevated, damage to the optic nerve can occur. Patients with elevated IOP but no detectable nerve damage are said to have "ocular hypertension." If nerve damage becomes detectable, the patient with elevated IOP now has glaucoma. Millions of people in the United States suffer from glaucoma and ocular hypertension, which, though not curable, are treated by medications that lower IOP.

Allergan's COMBIGAN® product, which Allergan spent over eight years to develop and obtain FDA approval for, is one such medication that allows patients to control their IOP levels and prevent the vision loss that comes from untreated pressure elevation.

The parties' dispute here concerns Allergan's patents on the innovative clinical treatment with COMBIGAN®, particularly its surprising efficacy and low rates of adverse events. The dispute began in November 2008 when Sandoz filed an abbreviated new drug application (ANDA No. 91-087) seeking approval to sell a generic version of Allergan's glaucoma drug COMBIGAN®. Sandoz's proposed product was an exact copy of Allergan's COMBIGAN®, with the same ingredients, same composition, and same proposed product labeling. (C.A. App. 4181–82.)

As envisioned by the Hatch-Waxman Act, Allergan brought suit in 2009 to stop Sandoz from launching its product before the expiration of Allergan's patents on using COMBIGAN®, including U.S. Patent Nos. 7,030,149 and 7,320,976. *See* 35 U.S.C. § 271(e)(4)(A). The patents cover treating glaucoma or ocular hypertension by applying a formulation with the two active ingredients in COMBIGAN®—"0.2% brimonidine" and "0.5% timolol"—to a patient's eye. Each ingredient is referred to in two different chemical forms: (1) a salt, in which a positively charged ion of brimonidine or timolol is bound to a negatively charged ion of some other substance or (2) a "free base," in which a neutral form of brimonidine or timolol is by itself, not bound.

A preliminary question in the 2009 suit was whether the patents used the terms "brimonidine" and "timolol" to refer to the salt form or the free base form. Allergan and Sandoz agreed that "brimonidine" in Allergan's patent claims means "brimonidine tartrate" (the salt form), and further agreed that "timolol" means "timolol free base" (the base form). (C.A. App. 3331–35.) The district court conducted its own

independent analysis before adopting those meanings. (*Id.*)

With those constructions of the two terms in place, the next question was whether, as a factual matter, Sandoz's proposed generic product had 0.2% brimonidine tartrate and 0.5% timolol free base. Sandoz stipulated that it did. In particular, Sandoz stipulated "that the proposed product described in ANDA No. 91-087 meets all of the limitations of claim 4 of U.S. Patent No. 7,030,149 [and] claim 1 of U.S. Patent No. 7,320,976." (C.A. App. 4672.) Sandoz also told the district judge in open court that Sandoz "agree[d] that we infringe under" 35 U.S.C. § 271(e)(2). (C.A. App. 3363-3364.)

Sandoz also made clear that its infringement stipulation was broad and binding in any future proceedings. Allergan had expressed concern that Sandoz might try to withdraw from the stipulation at a later date forcing Allergan to "have to come back to Your Honor and then try to prove up infringement again." (C.A. App. 3365.) Sandoz responded by stipulating that "Allergan can use this stipulation in any future proceeding relating to the subject matter of the present litigation, including if there is a launch at risk." (C.A. App. 4673.)

The reasons Sandoz made these admissions are clear. In the FDA's "Orange Book", the "strength" of Allergan's COMBIGAN® product is listed as 0.2% brimonidine tartrate and 0.5% timolol free base. Accordingly, Sandoz was simply admitting to something that the FDA required of its product in order for it to be a generic of COMBIGAN®—*i.e.*, that it had the same strength as Allergan's branded product.

Based on Sandoz's stipulation of fact, the district court found that Sandoz's abbreviated new drug application infringed Allergan's patents, found the patents valid, and enjoined Sandoz from launching its product. *See Allergan, Inc. v. Sandoz, Inc.,* 818 F. Supp. 2d 974 (E.D. Tex. 2011). Sandoz appealed validity to the Federal Circuit but didn't appeal the infringement finding. The Federal Circuit affirmed the validity of claim 4 of Allergan's '149 patent based on the unexpected clinical results achieved by COMBIGAN® and recited in the claim, affirmed the injunction, and thus found it unnecessary to reach the validity of the '976 patent. *See Allergan, Inc. v. Sandoz, Inc.*, 726 F.3d 1286 (Fed. Cir. 2013). This Court denied *certiorari*.

II. The District Court Permits Sandoz to Renege on its Prior Stipulation of Infringement in This Litigation.

Refusing to take "no" for an answer, Sandoz amended its ANDA (still No. 91-087) to try and avoid the prior infringement finding. Sandoz's amendment had nothing at all to do with the composition of its proposed product, nothing to do with "brimonidine" or "timolol," and nothing to do with the amounts of any ingredients used. (App. 67a–68a.) As the district court found, and as Sandoz acknowledges, the "revised" product remains an exact copy of COMBIGAN®, using the same components in the same amounts. (*Id.*)

The only change that Sandoz proposed making was to change the product labeling from reciting that it should be used to treat "glaucoma or ocular hypertension," to just say that it should be used for only "ocular hypertension." (C.A. App. 2330.) It wasn't clear

why Sandoz thought this would succeed, however, because Allergan's patents covered using the product for "treatment of glaucoma ***or*** ocular hypertension," (App. 58a, 60a–61a), and Sandoz still intended the product would be prescribed for both categories of patients in spite of the label amendment. (App. 98a–99a.)

Nevertheless, when Sandoz amended its label, under the Hatch-Waxman Act, Allergan was required to file the present lawsuit to stop Sandoz from launching its generic product with the revised labelling. This suit alleges that Sandoz infringes the same '149 and '976 patents from the prior litigation, along with a later-issued patent (No. 8,748,425). Like the '149 and '976 patents, the '425 patent contains method of treatment claims. But it specifically recites the use of a combination of 0.2% brimonidine tartrate and 0.5% timolol free base, based on what Sandoz stipulated was in its product. (App. 61a.)

Although Sandoz used its label revision to get this litigation started, it primarily used this litigation as an opportunity to re-litigate issues having nothing to do with that labelling amendment. In particular, Sandoz again challenged the validity of Allergan's patents, and, importantly for this petition, it now challenged whether its proposed product meets the "0.2% brimonidine" and "0.5% timolol" requirements of Allergan's '149 and '976 patents. Those were the very limitations that Sandoz had previously stipulated that its product met. Sandoz also challenged whether its product met the "0.2% brimonidine tartrate" and "0.5% timolol free base" requirements of Allergan's '425 patent, the same components that Sandoz had already admitted its product contained.

The district court correctly recognized that Sandoz's arguments about those limitations "had absolutely no relation to the amendment" it made to the label in its abbreviated new drug application. (App. 162a.) It further observed that "[s]ince the amended ANDA [abbreviated new drug application] did not give rise to any new arguments, [Sandoz's amended ANDA] was less a design around Allergan's patents and more a hypertechnical, if not illegal, end run around the injunction stemming from" the parties' prior litigation. (*Id.*) The district court ultimately concluded that the "only utility of Sandoz's amended ANDA was as a key to open the door to arguments that Sandoz regretted giving up in" the prior litigation. (*Id.*) Despite those comments, however, the district court permitted Sandoz to relitigate these issues anyway, with no explanation of why it was appropriate it do so.

Notably, the district judge from the parties' first case, Judge Ward, had retired, so the present case was assigned to a new judge, Judge Gilstrap. After pretrial matters concluded, the parties tried the case before Judge Gilstrap in a three-day bench trial in October 2016.

At trial, Sandoz's main argument was that it did not infringe the very same patents that it had stipulated it infringed in the prior litigation, as well as the '425 patent. (It also renewed all its identical validity arguments from before.) On non-infringement, Sandoz argued that, rather than containing 0.2% brimonidine tartrate and 0.5% timolol free base as it had previously admitted and as the FDA requires, its product really contained 0.2% brimonidine tartrate and 0.68% timolol maleate or, alternatively, 0.132% brimonidine free base and 0.5% timolol free base.

Despite Sandoz's prior binding stipulation, the district court inexplicably accepted Sandoz's arguments, and found that Sandoz's product did not contain 0.2% brimonidine tartrate as Sandoz had previously admitted, but instead contained 0.132% brimonidine free base. (App. 94a at ¶ 88.) On that basis, the district court then found that Sandoz's identical product did not infringe the very patents Sandoz had admitted the product infringed, the '149 and '976 patents. (App. 141a at ¶ 10.) Allergan vigorously argued that Sandoz's prior stipulation to infringement—a factual issue—blocked it from relitigating the matter in this case. And the district court acknowledged that Sandoz simply "regretted its stipulation" and sought to "relitigate infringement," even though "it could have made these identical non-infringement arguments in" the prior litigation. (App. 161a.) But the district court considered the arguments on the merits, without ever explaining why Sandoz's prior stipulation to infringement should be ignored.

The district court did find infringement of the '425 patent, which specifically recited "0.2% brimonidine tartrate" and "0.5% timolol free base," but for reasons unrelated to the stipulation. Distressingly, in over 100 collective pages of findings and fact and judgment, beyond mentioning its existence, the district court never once discussed Sandoz's prior stipulation that its product infringed the '149 and '976 patents—and thus contained those two ingredients—or its admission on the day before the first trial of the same.[1]

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[1] On validity, the court rejected Sandoz's attempts to relitigate the validity of the '149 and '976 patents, finding that, consistent with the Federal Circuit's validity findings in the first appeal, the claimed clinical results of those patents, and those of

III. The Federal Circuit Finds Non-Infringement of All Claims Without Addressing Sandoz's Prior Stipulation of Infringement.

Sandoz appealed the district court's validity finding and the infringement finding on the '425 patent to the Federal Circuit. Allergan cross-appealed the district court's non-infringement finding on the '149 and '976 patents.

The Federal Circuit, as it had in the first appeal, affirmed the district court's findings that the patents are valid and recite clinical inventions related to COMBIGAN®'s efficacy and adverse event profile that are not taught or suggested anywhere in the prior art. Accordingly, the inventions before this Court have now been found valid four times, twice by the district court and twice by the appellate court.

With the validity of Allergan's claimed methods of treatment using COMBIGAN® once again established, the Federal Circuit then turned to the parties' arguments on infringement. Allergan's lead infringement argument in both its appellate briefs was that the district court's non-infringement judgment should be reversed because Sandoz was bound by its prior stipulation of infringement from the first litigation. (*See* C.A. Dkt. No. 25 at 66–69; Dkt. No. 35 at 3–6.) Yet the Federal Circuit panel ignored the argument altogether, not addressing the stipulation at all in its opinion. (App. 1a–10a.)

Instead, the Federal Circuit panel found that the patents covered neither COMBIGAN® nor Sandoz's

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the '425 patent, were unexpected and not in the prior art. (App142a–149a.)

copycat product. (App. 8a–10a.) On the '149 and '976 patents, it agreed with the district court that the products contain 0.132% brimonidine. (App. 9a.) Without any further explanation, the panel concluded that the district court "did not err" in finding non-infringement of the '149 and '976 patents. On the '425 patent, the panel, also without mentioning the prior stipulation, concluded that the district court erred in finding infringement because the product does not contain 0.5% timolol free base, but instead contains 0.68% timolol maleate. (App. 8a–9a.)

Both of these findings contradict Sandoz's prior stipulation, as well as the FDA's notation of the strength of the product in the Orange Book.

Allergan sought rehearing and rehearing *en banc*, where, once again, its lead argument was that Sandoz's prior stipulation of infringement—a factual issue—precluded it from re-litigating the matter now. (C.A. Dkt. No. 60 at 1–4, 10–14.) The Federal Circuit denied rehearing without comment. (App. 182a–183a.)

REASONS FOR GRANTING THE PETITION

The Federal Circuit's refusal to enforce, or even acknowledge, Sandoz's factual stipulation of infringement of Allergan's valid patents on COMBIGAN® should be summarily reversed. Stipulations of fact are universally enforced where, as here, there is no reason to allow a party to renege. It is important to ensure such stipulations are enforced—otherwise, it discourages parties from entering them, ultimately wasting significant court and party resources. Stipulations are common in every type of case, so allowing the Federal Circuit's decision to stand will have a wide-ranging negative impact. At a minimum, this

Court should vacate the Federal Circuit's decision with instructions for it to actually address the issue and explain its reasoning.

I. The Federal Circuit's Refusal to Enforce the Stipulation of Fact Should Be Reversed or Vacated.

A. There Is No Basis to Refuse to Enforce Sandoz's Stipulation of Fact.

1. Both this court and the lower courts have universally recognized that stipulations of fact are binding and will be enforced. This Court has summarized the rule clearly, quoting from a well-respected treatise on the subject:

> [Factual stipulations are] binding and conclusive ..., and the facts stated are not subject to subsequent variation. So, the parties will not be permitted to deny the truth of the facts stated, ... or to maintain a contention contrary to the agreed statement, ... or to suggest, on appeal, that the facts were other than as stipulated or that any material fact was omitted.

Christian Legal Society Chapter of the Univ. of Hastings of California v. Martinez, 561 U.S. 661, 677 (2010) (quoting 83 C.J.S., Stipulations § 93 (2000)). And this rule has been settled for a long time. *See H. Hackfeld & Co. v. United States*, 197 U.S. 442, 447 (1905) ("[P]arties [a]re entitled to have [their] case tried upon the assumption that . . . facts, stipulated into the record, were established."); *Oscanyan v. Arms Co.*, 103 U.S. 261, 263 (1881) ("The power of the court to act in the disposition of a trial upon facts conceded by counsel is as plain as its power to act upon the evidence produced."). "This Court has accordingly refused to consider a party's argument that contradicted

a joint stipulation [entered] at the outset of th[e] litigation." *Martinez*, 561 U.S. at 677 (alternations in original). "[F]actual stipulations are 'formal concessions ... that have the effect of withdrawing a fact from issue and dispensing wholly with the need for proof of the fact.'" *Id. (quoting* 2 K. Broun, MCCORMICK ON EVIDENCE § 254, p. 181 (6th ed.2006) (footnote omitted)).

The Courts of Appeals, including the Federal Circuit, have previously recognized the same rule. *See, e.g., United States v. Bill Harbert Int'l Construction, Inc.*, 608 F.3d 871, 889 (D.C. Cir. 2010) ("Stipulations of fact bind the court and parties. This is their very purpose, their vital feature. Once a stipulation of fact is made, the one party need offer no evidence to prove it and the other is not allowed to disprove it."); *Gander v. Gander*, 250 F.3d 606, 609 (8th Cir. 2001) ("Stipulations by the parties regarding questions of fact are conclusive. Trial courts are bound by the facts established by the stipulation. Valid stipulations are controlling and conclusive, and courts must enforce them. Courts cannot make contrary findings."); *Hernandez v. Philip Morris USA, Inc.*, 486 F.3d 1, 6 (1st Cir. 2007) ("Once a party has entered into a stipulation, however, that party is not at liberty to renege unilaterally on a stipulated fact without leave of court, which ordinarily will not be granted absent a showing of good cause."); *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1546 (Fed. Cir. 1994) (rejecting attempt to avoid a stipulation and explaining that "public policy favors preventing Chrysler from reneging on an agreement into which it freely entered and upon which Kearns and the district court relied"); *Fisher v. First Stamford Bank & Trust Co.*, 751 F.2d 519, 523 (2d Cir. 1984) ("Generally, a stipulation of fact that is fairly entered into is controlling on the parties and the court is bound to enforce it.").

There is good reason why stipulations are sacrosanct and so readily enforced—they save judicial resources and avoid subjecting a prevailing party to an unfair "redo" of a case it already won. *See, e.g., Hernandez*, 486 F.3d at 5 ("Stipulations eliminate the need for proving essentially uncontested facts, thus husbanding scarce judicial resources. Since stipulations are important to the efficient and expeditious progress of litigation in the federal courts, parties are encouraged to stipulate as to factual matters."); *Waldorf v. Shuta*, 142 F.3d 601, 616 (3d Cir. 1998) ("In general, courts encourage parties to enter into stipulations to promote judicial economy by narrowing the issues in dispute during litigation. Allowing parties easily to set aside or modify stipulations would defeat this purpose, wasting judicial resources and undermining future confidence in such agreements.").

2. There is no basis not to enforce Sandoz's stipulation of infringement given the clear law above. The stipulation was a factual one, as "[i]nfringement is a question of fact." *See, e.g., Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1382 (Fed. Cir. 2008). The stipulation could not be clearer that Sandoz was agreeing that its proposed generic product contained "0.2% brimonidine tartate" and "0.5% timolol free base," as required by the '149 and '976 patents at issue in the first case and again here, and as required by the '425 patent that Allergan obtained after Sandoz had stipulated that its product contained those components. The stipulation provided that "that the proposed product described in ANDA No. 91-087 meets all of the limitations of claim 4 of U.S. Patent No. 7,030,149 [and] claim 1 of U.S. Patent No. 7,320,976." (C.A. App. 4672.) Those "limitations," as construed by the court in that case included that requirements that the product have "0.2%

brimonidine tartrate" and "0.5% timolol free base." (C.A. App. 3331–35.) Sandoz's lawyer also told the district judge in open court that Sandoz "agree[d] that we infringe under" 35 U.S.C. § 271(e)(2). (C.A. App. 3363-3364.) The district court adopted that same understanding in finding infringement in the 2009 case. *See Allergan*, 818 F. Supp. at 1000–01 ("[T]here is no dispute between the parties that each of the Defendants infringes each of the asserted claims pursuant to 35 U.S.C. § 271(e)(2).").

What's more, the stipulation itself made clear that it was applicable in future cases, such as this one. The stipulation provides that "Allergan can use this stipulation ***in any future proceeding relating to the subject matter of the present litigation***, including if there is a launch at risk." (C.A. App. 4673 (emphasis added).) That describes this case to a T. The "subject matter" here is plainly the same as the first litigation. It involves the same abbreviated new drug application with the same number (No. 91-087). As the district court found, Sandoz's proposed product still had the exact same ingredients and exact same composition as before. (App. 67a–68a.) And, as the court also found, Sandoz's non-infringement arguments "had absolutely no relation to the amendment" to its proposed labeling. (App. 162a.) Sandoz simply "regretted its stipulation" and sought to "re-litigate infringement," even though "it could have made these identical non-infringement arguments in" the prior litigation. (App. 161a.)

3. Given the clarity of the law and facts here, this Court should summarily reverse the Federal Circuit, enforce the stipulation, and enter judgment that Sandoz's proposed generic product still infringes the

'149 and '976 patents and also infringes the '425 patent. This Court has not hesitated to summarily reverse the courts of appeals where, as here, they ignore well-established law. *See, e.g., Kisela v. Hughes*, 138 S. Ct. 1148 (2018) (*per curiam*); *CNH Industrial, N.V. v. Reese,* 138 S. Ct. 761 (2018) (*per curiam*); *Dunn v. Madison,* 138 S. Ct. 9 (2017) (*per curiam*). Summary reversal is the appropriate course here, because it would correct the egregious error below while saving this Court the time and resources associated with setting the case for full briefing and argument. Without this Court's intervention, parties cannot feel confident that the Federal Circuit that the Federal Circuit will enforce their factual stipulations.

B. At a Minimum, the Federal Circuit Should Be Instructed to Address the Stipulation.

The lower courts' legal error in not enforcing the stipulation was particularly problematic, because they did not even address its applicability. The Federal Circuit opinion did not mention the stipulation at all. (App. 1a–10a.) And although the district court mentioned that the stipulation existed, (App. 64a at ¶ 25), it never analyzed whether it binds Sandoz in this case, much less did it give any reason why Sandoz should be permitted to renege on it to escape liability for infringement of Allergan's valid patents. This failure to address Allergan's lead infringement argument was legal error that, at a minimum, warrants a remand with instructions for the Federal Circuit to address the issue.

1. Federal courts have a duty to explain the bases of their decisions. *See, e.g., In re United States*, 138 S. Ct. 443 (2017) (summarily vacating where the

lower courts failed to consider a party's "serious arguments" and ordering that it should not be compelled to produce documents "without first providing" the party "with the opportunity to argue the issue"). Article III judges are not elected, and they derive their legitimacy in large part from writing decisions justifying the results that they reach. A lower court's failure to address a party's principal argument undermines public confidence in the judiciary. And it greatly increases the risk of error, because the court can avoid grappling with law or fact that is contrary to its desired result.

Recognizing the importance of reasoned decisionmaking, this Court has required lower courts to adequately explain how they arrived at criminal sentencing decisions. *See, e.g., Gall v. United States*, 552 U.S. 38, 50 (2007) (holding a district judge "must adequately explain the chosen sentence to allow for meaningful appellate review and to promote the perception of fair sentencing"); *Rita v. United States*, 551 U.S. 338, 356 (2007) ("The sentencing judge should set forth enough to satisfy the appellate court that he has considered the parties' arguments and has a reasoned basis for exercising his own legal decisionmaking authority").

Likewise, both this Court and the lower courts have required that federal agencies adequately explain themselves under the Administrative Procedure Act. *See, e.g., Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 46 (1983) (finding an agency action arbitrary and capricious where it "gave no consideration" of important evidence); *Phelps Dodge Corp. v. N.L.R.B.*,

313 U.S. 177, 197 (1941) (requiring an agency to provide a "clear indication that it has exercised the discretion with which Congress has empowered it" because "[t]he administrative process will best be vindicated by clarity in its exercise."); *SecurityPoint Holdings, Inc. v. Transportation Sec. Admin.*, 769 F.3d 1184, 1187–88 (D.C. Cir. 2014) ("The agency's statement must be one of reasoning; it must not be just a conclusion; it must articulate a satisfactory explanation for its action" such that a reviewing court "could conclude that it was the product of reasoned decisionmaking."); *Butte Cty., Cal. v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010) ("[A]n agency's refusal to consider evidence bearing on the issue before it constitutes arbitrary agency action…."). Courts should demand no less of themselves.

2. The Court should apply these same principles in this case. Allergan's principal infringement argument at the Federal Circuit was that the stipulation was binding. (*See* C.A. Dkt. No. 25 at 66–69; Dkt. No. 35 at 3–6.) Yet that Court never once mentioned it. To be sure, the Federal Circuit's opinion included a catch-all at the end, saying that "[w]e have considered remaining arguments and find them unpersuasive." (App. 10a.) But that is insufficient without some explanation, however brief, of ***why*** the arguments were unpersuasive. An explanation was particularly important in this case, given that the law and facts set forth above make it abundantly clear that the Federal Circuit should have enforced the stipulation. As it is, the public can have no confidence that the Federal Circuit seriously analyzed the relevant law, much less reached a reasoned decision here.

C. This Case Presents an Important Issue that Warrants this Court's Intervention.

1. The Federal Circuit's decision was not only plainly wrong but has the potential for widespread adverse consequences if allowed to stand. Factual stipulations are a part of almost every case, civil or criminal. Courts will be unable to efficiently dispose of cases if parties have no assurance that they can rely on stipulations of fact. Instead, parties will be motivated to prove every fact, even if uncontested, resulting in a wasted expenditure of court time and effort. This result is particularly problematic for patent cases, which are already one of the more technically complex types of litigation that the federal courts face.

The facts of this case exemplify the waste of judicial resources that will occur. The lower courts' failure to enforce (or even discuss) the stipulation has led them to prolong litigation that has ongoing for almost a decade. It led them to the odd conclusion that Allergan's patents do not cover either Allergan's own product (COMBIGAN®) or Sandoz's proposed generic product, even though Sandoz had stipulated to infringement in the first case despite having every incentive to contest it. The result has been to force Allergan to obtain a new patent to eliminate Sandoz's belated argument and file yet another case to protect its substantial investment in developing COMBIGAN®. *See Allergan Sales, LLC v. Sandoz, Inc.*, Case No. 2:17-cv-10129 (D.N.J.). Allergan has had to file a preliminary injunction motion in that litigation to ensure that Sandoz does not launch its product before the case can be decided, which would likely destroy Allergan's market for COMBIGAN®. None of that should be necessary. This dispute should have ended in 2014, after

this Court denied *certiorari* in the first litigation. Instead, it will carry on for years to come, absent this Court's intervention.

2. This Court's review is also warranted, because Federal Circuit's decision departs from this Court's precedent and splits with every other circuit to consider the issue. *See* cases cited at pp. 13–14. What's worse, it again creates a patent-specific rule where factual stipulations are not enforceable in patent cases, even though they are enforceable in every other type of case. This Court has warned against such results. *See, e.g., eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) (reversing a patent-specific rule for injunctions and explaining that general equitable principles "apply with equal force to disputes arising under the Patent Act").

3. Finally, the manner in which this case was decided below warrants attention from this Court. The Federal Circuit did not mention the stipulation at all, much less any of the black-letter law that it departed from. If this Court is to have confidence that the lower courts are correctly applying the law, then they must explain their decisions, however briefly. Allowing lower court decisions to stand that do not explain their reasoning will impede this Court's ability to supervise them. It might also invite lower courts to avoid grappling with arguments that are contrary to the result they wish to reach by not discussing them, leading to erroneous decision-making that is difficult to detect.

CONCLUSION

For the reasons above, the Court should grant the petition and summarily reverse or vacate and remand with instructions for the Federal Circuit to address

whether Sandoz's stipulation requires a finding of infringement here on the '149, '976, and '425 patents.

Respectfully submitted,

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