No. 2015-1499

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMGEN INC., AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

v.

SANDOZ, INC.,

Defendant-Appellee.

Appeal from the United States District Court for the Northern District of California
In Case No. 3:14-cv-04741, Judge Richard Seeborg

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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STATEMENT OF IDENTITY OF AMICUS AND ITS INTEREST IN THE CASE AND AUTHORITY TO FILE

Pursuant to Federal Rule of Appellate Procedure 29(a)(2), the United States files this amicus brief to address whether the Biologics Price Competition and Innovation Act of 2009 (BPCIA) preempts additional remedies under state law for an applicant's failure to comply with 42 U.S.C. § 262(*l*)(2)(A).

STATEMENT

In its original decision in this case, this Court held that a sponsor is not entitled to an injunction under either the BPCIA or California's Unfair Competition Law (UCL) to enforce a biosimilar applicant's disclosure obligation under § 262(*l*)(2)(A). The Supreme Court agreed that "an injunction under federal law is not available" because Congress deliberately omitted injunctive relief from the BPCIA's remedies for noncompliance with that provision. *Sandoz, Inc. v. Amgen, Inc.*, 137 S. Ct. 1664, 1674 (2017). But the Court remanded for this Court to reconsider whether Amgen is entitled to a remedy under the UCL. *See id.* at 1676. The Supreme Court directed this Court to determine on remand whether Sandoz's noncompliance with § 262(*l*)(2)(A) would be treated as "unlawful" for purposes of the UCL's remedies for "unlawful" business practices; whether Sandoz has forfeited any pre-emption defense to such a claim; and if not, whether the BPCIA "pre-empts any additional remedy available under state law for an applicant's failure to comply with § 262(*l*)(2)(A)." *Id.* at 1676-77.

ARGUMENT

The BPCIA Preempts Any Additional Remedy That May be Available Under State Law for an Applicant's Failure to Comply With Section 262(*l*)(2)(A) of the BPCIA.

The BPCIA preempts any state-law remedies for an applicant's decision not to make the disclosures identified in Section 262(*l*)(2)(A). Section 262(*l*) and other federal statutes occupy the field of federal patent litigation, precluding states from regulating the procedures concerning such litigation. Allowing additional state law remedies also would impair important objectives the BPCIA's patent-related provisions are designed to achieve.

1. The Supremacy Clause precludes states from regulating conduct "in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance." *Arizona v. United States*, 132 S. Ct. 2492, 2501 (2012). "Where Congress occupies an entire field * * * even complementary state regulation is impermissible." *Id.* at 2502. Congress's intent to displace state law altogether can be express, or "inferred from a framework of regulation 'so pervasive . . . that Congress left no room for the States to supplement it' or where there is a 'federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Id.* at 2501 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

While Congress has not occupied the field of patent law or intellectual property law more generally, *see Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 154-56 (1989), Congress has occupied the field of federal patent *litigation*. Congress has assigned the federal courts exclusive jurisdiction over claims arising under the patent laws, *see Gunn v. Minton*, 133 S. Ct. 1059, 1062 (2013), and has expressly barred state courts from entertaining such claims. *See* 28 U.S.C. § 1338(a) ("No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents"). The procedures governing the presentation of patent claims and defenses are controlled by federal laws and the Federal Rules of Civil Procedure. As a result, states lack the authority to proscribe their own procedural rules for federal patent litigation or their own remedies for violations of the rules prescribed under the Rules Enabling Act and other federal laws. *Cf. Hanna v. Plumer*, 380 U.S. 460, 465 (1965) (pursuant to the Rules Enabling Act and the *Erie* doctrine, "federal courts are to apply state substantive law and federal procedural law").

The procedural rules set forth in 42 U.S.C. § 262(*l*), including the disclosure provision in § 262(*l*)(2)(A), constitute an additional set of federal requirements for a specific subset of federal patent disputes: claims based on artificial patent infringement under the BPCIA. States have no more authority to regulate those procedural rules than they have over any other aspect of federal patent litigation.

Together with the pre-existing body of federal laws and rules governing the adjudication of federal patent claims, the BPCIA leaves the states no room to prescribe or enforce procedural rules pertaining to biosimilar patent infringement claims. *Cf. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-48 (2001) (states lack the authority to regulate the relationship between a federal agency and the entity it regulates because that relationship "originates from, is governed by, and terminates according to federal law").[1]

The case for field preemption is reinforced by the comprehensiveness with which the BPCIA regulates patent litigation relating to biosimilars. In *Arizona*, the Supreme Court concluded that Congress had preempted the field of alien registration because it had created a "comprehensive" and "'integrated'" scheme of regulation that includes both standards and consequences for noncompliance. 132 S. Ct. at 2502. Accordingly, "[p]ermitting the State to impose its own penalties for the federal offenses here would conflict with the careful framework Congress adopted." *Id.* So too here. As the Supreme Court emphasized, Congress in

[1] In arguing against field preemption, Amgen relies on this Court's observation in *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1333 (Fed. Cir. 1998), that federal patent law does not "occupy exclusively the field pertaining to state unfair competition law." As the foregoing discussion indicates, Amgen's argument mischaracterizes the relevant field. Whether or not federal law preempts the field of state unfair competition laws, it unquestionably occupies the field of federal patent *litigation*, including the procedures by which such litigation is conducted. *Rodime PLC v. Seagate Technology, Inc.*, 174 F.3d 1294 (Fed. Cir. 1999), is inapposite for similar reasons.

enacting the BPCIA created "a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of [patent] infringement" between sponsors and applicants. *Sandoz*, 137 S. Ct. at 1670. Allowing states to impose their own remedies and sanctions would intrude on that "carefully calibrated scheme." *See also Buckman*, 531 U.S. at 347-48; *Wisconsin Dep't of Industry v. Gould Inc.*, 475 U.S. 282, 289 (1986) (States may not impose their own punishment for repeat violations of the National Labor Relations Act). Allowing fifty states to provide additional remedies to the existing procedural requirements in § 262(*l*) would undermine the uniformity of the federal scheme, subjecting applicants and sponsors to different, and potentially inconsistent, state-law remedies. *Cf. Buckman*, 531 U.S. at 350 ("As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA."). The Chief Justice expressed concern over the impact of divergent and potentially inconsistent state remedies during the oral argument in this case. *See* Tr. 49 ("[I]f we apply California law, then, presumably, in some circumstances, we apply the law of every other State and maybe they reach different consequences.").

This Court recognized the force of similar concerns in *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013), *cert. denied*, 135 S. Ct.

2886 (2015). Although the Court rejected the defendant's argument that the Federal Food, Drug, and Cosmetic Act preempted the plaintiff's state law suit in that case, it did so on grounds that are inapposite here.[2] More importantly, the Court nevertheless recognized that a nationwide injunction would "usurp the discretionary enforcement authority of the FDA" by permitting California "to stand in the shoes of the FDA to determine whether [petitioner's] sale of the products at issue amounts to the sale of an unapproved drug under the FDCA." *Id.* at 1358-59. To avoid that outcome, the Court confined the scope of the state-law injunction (regarding the marketing of a particular product) to the state of California. Here, the kind of injunction sought by Amgen under California law to compel disclosure of information concerning the nationwide marketing of a biosimilar does not lend itself to comparable geographic tailoring: an order compelling an applicant to provide such information to a sponsor is ineluctably nationwide in effect.

2. Assuming *arguendo* that Amgen's UCL claim states a cause of action under California law, it also would "'stand as an obstacle to the accomplishment

[2] Unlike in *Athena*, the UCL claim here does not involve a traditional subject of state tort law, but instead a patent dispute resolution process that "originates from, is governed by, and terminates according to federal law." *Buckman*, 531 U.S. at 347. The state tort law context at issue in *Athena* was critical to this Court's finding of no federal preemption there. *See* 738 F.3d at 1355. Relatedly, because Amgen is pursuing a state-law claim regarding a field (federal patent litigation) that does not involve the states' traditional authority to regulate the primary conduct of private parties, no presumption against preemption applies. *See Buckman*, 531 U.S. at 347-38.

and execution of the full purposes and objectives of Congress.'" *Arizona*, 132 S. Ct. at 2500. That is true regardless of whether the disclosures Section 262(*l*)(2)(A) identifies are viewed as a condition precedent for invoking subsection (*l*)'s patent-dispute framework, or as imposing a legal duty. *See Sandoz*, 132 S. Ct. at 1676.

a. This Court earlier concluded that an applicant does not violate the BPCIA when it declines to provide the sponsor with the information specified by § 262(*l*)(2)(A). *See Amgen, Inc. v. Sandoz, Inc.*, 794 F.3d 1347, 1357, 1360 (Fed. Cir. 2015); *see also id.* at 1367 (Chen, J., concurring in relevant part and dissenting in part). Rather, the Court concluded the applicant is following "a path expressly contemplated by the BPCIA." *Id.*at 1357. Under this view, the BPCIA provides applicants a choice regarding pre-approval patent litigation. The applicant may provide the sponsor with specified proprietary information about the biosimilar, in which case the statute gives it a substantial measure of control over the dimensions of the initial round of patent litigation. Alternatively, the applicant may choose to withhold the information, in which case the statute deprives it of that control, allowing the sponsor to bring an infringement action with respect to claims of its own choosing while the applicant is barred from initiating its own pre-approval challenges to the sponsor's patents. *See Sandoz*, 127 S. Ct. at 1675.

Even assuming *dubitante* that Sandoz acted "unlawfully" under the UCL on this view of the BPCIA, a state-law injunction compelling the applicant to make

initial disclosures under § 262(*l*)(2)(A) would block "a path expressly contemplated by the BPCIA," and deprive the applicant of a choice the BPCIA was designed to provide. In so doing, state law would obstruct the BPCIA's purposes and objectives. *Cf. Geier v. American Honda Motor Co.*, 529 U.S. 861, 865, 881 (2000) (state tort law imposing a duty on manufacturers to install a driver's-side airbag in all new cars conflicts with, and is preempted by, federal regulations that provide manufacturers with "a choice as to whether to install airbags"). Justice Sotomayor made this point in the *Sandoz* oral argument, noting that to allow state law injunctions would mean that whether to provide the disclosures § 262(*l*)(2)(A) identifies is "no longer a choice" for the applicant. Tr. 52. Moreover, this problem is not confined to § 262(*l*)(2)(A); at *every* stage in the statutory scheme, as Justice Sotomayor pointed out, recognizing state law authority to obtain an injunction would effectively allow the parties to force disclosures and exchanges that the BPCIA allows the parties to "opt out" of. Tr. 52.[3]

Allowing a sponsor to sue under state law to enforce § 262(*l*)(2)(A)'s disclosure requirement also has the potential to interfere with the BPCIA's goal of

[3] These arguments also encompass the retrospective award of restitution. Under the view of the statute previously adopted by this Court, such an award would conflict with the choice that Congress has vested in the applicant and Congress's own judgment regarding the appropriate consequences of that choice. Moreover, the risk of financial liability would also distort applicants' decisions that would otherwise be governed by the BPCIA's comprehensive federal framework.

expediting the resolution of biosimilar patent disputes. Congress imposed short and fixed statutory time limits on each of the prescribed steps in 42 U.S.C. § 262(*l*)(2) through (*l*)(6), leading to the commencement of patent litigation no more than roughly 250 days after FDA accepts the applicant's biosimilar application for review. To allow a private party to sue under state law for an injunction enforcing § 262(*l*)(2)(A) would undermine that timetable by allowing for potentially lengthy collateral litigation over compliance with § 262(*l*)(2)(A). Even where the applicant provides information pursuant to that provision, there may well be disagreements about whether the information provided is sufficient to satisfy the requirements of the statute. Collateral litigation over compliance could require an extended period to resolve, and the remaining steps in Sections 262(*l*)(2) through (*l*)(6) could not begin, much less be completed, until that litigation had run its course.

b. Relying primarily on Congress's use of the word "shall" to frame the applicant's disclosure obligation under § 262(*l*)(2)(A), Judge Newman concluded that compliance with that provision is a legal duty and that a decision not to provide the information constitutes a "deliberate violation[] of the requirements of the BPCIA." 794 F.3d at 1362-63 (Newman, J., concurring in part and dissenting in relevant part). But even if Sandoz acted "unlawfully" under the UCL on this view of the BPCIA, the requested state-law injunction would still undermine Congress's determination not to authorize additional remedies for noncompliance

with § 262(*l*)(2)(A) beyond the remedy specified in the BPCIA. *See Sandoz*, 137 S. Ct. at 1675. It would intrude on Congress's comprehensive and "carefully calibrated scheme," *id.* at 1670, for initiating artificial patent infringement suits and Congress's equally careful elaboration of the appropriate remedies for failures to follow the statutory procedures. *Cf. Arizona*, 132 S. Ct. at 2504-05 (comprehensive federal framework for combatting employment of illegal aliens preempted state law imposing criminal penalties on aliens for working without federal work authorization, where Congress deliberately chose not to impose criminal penalties for such conduct).[4]

CONCLUSION

For the foregoing reasons, the Court should hold that the BPCIA preempts any additional remedy that may be available under state law for an applicant's failure to comply with § 262(*l*)(2)(A).

[4] Finally, we note the Supreme Court's statement that the parties' dispute over whether § 262(*l*)(2)(A) imposes a legal duty or a condition precedent "does not present a question of federal law." 137 S. Ct. at 1676. That statement arguably reflects that Amgen's UCL claim necessarily rests on the state-law question of what types of conduct could qualify as a "unlawful" (*e.g.*, any prohibited conduct or only that carrying an independent sanction or some similar criterion), and the related recognition that any interpretation of the BPCIA under federal law therefore occurs only after that antecedent state-law question has been resolved. But even if the Court's statement might be read to suggest that the BPCIA simply says nothing about the proper characterization of § 262(*l*)(2)(A)'s requirements, then Amgen could not establish that noncompliance is "unlawful" under the UCL, and this Court would not need to reach the preemption issue.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the length limitation set forth in Federal Rule of Appellate Procedure 29(a)(5) because the brief is 10 pages (one-half the length for the parties' briefs as set by this Court's order of July 26, 2017), excluding those parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(f) and Federal Circuit Rule 32(b). I further certify that the brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the style requirements of Federal Rule of Appellate Procedure 32(a)(6) because the brief has been prepared in 14-point Times New Roman, which is a proportionally spaced typeface, using Microsoft Word.

s/Lowell V. Sturgill Jr.
Lowell V. Sturgill Jr.

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on September 11, 2017.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

s/Lowell V. Sturgill Jr.
Lowell V. Sturgill Jr.