No. 2015-1499

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-RS, Judge Richard Seeborg

BRIEF OF THE BIOSIMILARS COUNCIL AS AMICUS CURIAE IN SUPPORT OF APPELLEE

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September 5, 2017

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC., ET AL. V. SANDOZ INC.

No. 2015-1499

CERTIFICATE OF INTEREST

Counsel for The Biosimilars Council certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

The Biosimilars Council

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All corporations and publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

The Biosimilars Council is a division of the Association for Accessible Medicines.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court **(and who have not or will not enter an appearance in this case)** are:

None.

August 30, 2017
Date

/s/ William M. Jay
William M. Jay

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INTEREST OF AMICUS CURIAE[1]

The Biosimilars Council (the "Council"), a division of the Association for Accessible Medicines ("AAM"), represents the companies and stakeholder organizations working to develop biosimilar products for the U.S. market. AAM, formerly named the Generic Pharmaceutical Association, and its members worked to secure passage of the Biologics Price Competition and Innovation Act ("BPCIA"), and Council members have launched or intend to launch biosimilars through the BPCIA's expedited FDA approval and streamlined patent litigation pathways. They therefore have a significant interest in the correct interpretation of the BPCIA and the preservation of the careful balance Congress struck.

SUMMARY OF ARGUMENT

The BPCIA was enacted against a backdrop of comprehensive federal regulation of biologic approval and patent litigation that takes place exclusively in federal courts. The subject matter of the BPCIA—biosimilar approval and related patent litigation—involves "a scheme of federal regulation so pervasive" that there remains no role for state law to play. *Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.*, 196 F.3d 1366, 1372 (Fed. Cir. 1999) (citation omitted). Furthermore, subjecting biosimilar applicants to potential litigation in 50 States under 50 sets of

[1] All parties have consented to the filing of this brief. No party's counsel authored the brief in whole or in part, and no person other than *amicus*, its members, and its counsel contributed money intended to fund the brief's preparation or submission.

state rules would disrupt the careful balance between innovation in biologics and access to biosimilars that Congress struck, and turn a carefully calibrated patent resolution process into a chaotic and uncertain endeavor. Any such frustration of Congress's clear purposes is preempted.

ARGUMENT

I. The BPCIA Creates a Comprehensively Federal Field, Regulating The Federal Approval Of Biosimilars And The Timing And Procedure For The Related Patent Litigation.

If this Court takes up the preemption issue instead of remanding it to the district court, then the question is whether Congress, in enacting the BPCIA, intended to allow 50 different sets of state laws to regulate compliance with the BPCIA's patent-litigation provisions. The answer is no. The comprehensively federal nature of the subject matter leaves no room for state-law supplementation.

Both the process of approving a biosimilar application and the procedure for litigating patent infringement based on such an application are "inherently federal in character" because they are governed entirely by federal law and are not part of a field that States have traditionally occupied. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001). Thus, "no presumption against pre-emption obtains in this case." *Id.* at 348; *accord, e.g., United States v. Locke*, 529 U.S. 89, 108 (2000); *Biotech. Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362, 1373 (Fed. Cir. 2007) (*BIO*) (holding drug price law preempted by patent laws without

applying any presumption against preemption).

Indeed, precisely the opposite presumption should be afforded where, as here, Congress was legislating under the background presumption that state law would *not* play a role. The BPCIA regulates patent litigation touched off by the submission of a biosimilar application. Both patent *rights* and patent *litigation* are entirely creatures of federal law[2] and have not historically been matters of state regulation. The regulation of procedure in a case before a federal tribunal is an inherently federal subject, *see, e.g.*, *In re Loney*, 134 U.S. 372, 375 (1890), and that is doubly so when the case falls within *exclusive* federal jurisdiction. *Cf. Int'l Shoe Co. v. Pinkus*, 278 U.S. 261, 265-66 (1929) (bankruptcy) ("The national purpose to establish uniformity necessarily excludes state regulation."). These matters are "the type of regulation that demands a uniform national rule." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 163 (1989) (citation omitted).

Thus, this is a textbook case of field preemption—the BPCIA's biosimilar-approval and patent-litigation provisions "address[] 'a federal interest . . . so dominant that the federal system [is] assumed to preclude enforcement of state laws on the same subject.'" *Univ. of Colo.*, 196 F.3d at 1372 (ellipsis in original) (citation omitted). The BPCIA also involves "'a scheme of federal regulation so pervasive' that no room remains for a state to supplement." *Id.* (citation omitted).

[2] *See* 28 U.S.C. § 1338; *Abbott Labs. v. Brennan*, 952 F.2d 1346, 1355 (Fed. Cir. 1991) ("The patent grant is within the exclusive purview of federal law.").

Its patent-litigation provisions are "carefully crafted and detailed," creating a comprehensive procedural roadmap and specific consequences for departing from it. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1674-75 (2017). Congress "intentionally" provided for injunctive relief in one circumstance only, *id.* at 1675, and for no damages remedy at all. Amgen's unsupported argument (at 16-18) that the States can supply additional remedies they think more "meaningful" misses the point: Congress left no room for states to legislate in this field.

Amgen argues that this Court has already held that federal patent law does not oust state unfair competition law. Amgen Br. 15 (citing *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318 (Fed. Cir. 1998)). But the preemption claim here concerns the BPCIA, not patent law writ large, and specifically biosimilar *patent litigation*, a field that is exclusively federal and has not "coexisted harmoniously" with any overlapping state law "for almost 200 years," *Hunter Douglas*, 153 F.3d at 1334.

Because the BPCIA creates an exclusively federal field, state law could enter the BPCIA's domain only if Congress clearly invited it in. Congress did no such thing. That is enough to end the inquiry.

II. Litigation Under 50 States' Laws, In Regional Circuits And State Courts, Would Obstruct The Balanced System Congress Adopted To Bring Competition To High-Priced Biologic Drugs.

Even if Congress had not occupied the field of biosimilar approval and

related patent litigation, conflict preemption prohibits States from adding remedies to Congress's carefully calibrated statutory scheme. *See English v. Gen. Elec. Co.*, 496 U.S. 72, 79 n.5 (1990) (preemption categories not "rigidly distinct" and "field pre-emption may be understood as a species of conflict pre-emption"). Amgen's brief never confronts the reason why conflict preemption applies: not because Amgen's claims are related to a patent case, but because they are an impermissible attempt to use state law to enforce a federal statute with remedies Congress intentionally declined to provide. *See generally Buckman*, 531 U.S. at 348-53.[3]

A. Allowing States To Add Remedies To The BPCIA Would Upset The Balance Between Biosimilar and Biologic Manufacturers.

As discussed above, the BPCIA is a highly reticulated statute in which Congress dictated a step-by-step process for sequencing patent litigation, and consequences for either side's failure to follow it. In vacating and remanding, the Supreme Court expressly acknowledged that Congress *could have* permitted

[3] Amgen claims conflict preemption applies *only* when state-law claims do not "include additional elements not found in . . . federal patent law" or impermissibly "offer patent-like protection to subject matter addressed by federal law." Amgen Br. 12 (citing *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1306 (Fed. Cir. 1999)). That is an artificially narrow test. State law is preempted whenever it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *BIO*, 496 F.3d at 1372 (citation omitted). That is so whether or not the state cause of action involves elements not found in federal patent law, as virtually all state-law claims do. *See, e.g.*, *id.* at 1374 (law "penalizing high prices" preempted by federal patent law). Moreover, the state-law claims in *Rodime* stood entirely apart from federal patent law; they did not seek to enforce a federal statute with remedies Congress had declined to provide.

injunctive relief for failures to follow this process, but did not, and that "[t]he BPCIA's carefully crafted and detailed enforcement scheme provides strong evidence" that the omission was intentional. *Sandoz*, 137 S. Ct. at 1675 (citation omitted). The monetary award Amgen seeks is equally unavailable. A state law that overrides Congress's remedial judgment is preempted "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *E.g.*, *Arizona v. United States*, 567 U.S. 387, 406 (2012) (citation omitted).

The BPCIA's enforcement scheme, including its choice of remedies, reflects a conscious balance between protecting innovation in biologics and encouraging much-needed, less-costly biosimilars. *See* Jon Tanaka, *"Shall" We Dance? Interpreting the BPCIA's Patent Provisions*, 31 Berkeley Tech. L.J. 659, 681-82 (2016) (Congressional "hearings make clear that the specifics of the patent dispute resolution provisions were important to the generic industry, the innovator industry, and Congress in creating a balanced biosimilar regulatory scheme"). Congress was well aware that the incredible cost of patent litigation, and the resulting uncertainty about the timing and cost of market access, can chill investment in biosimilar development.[4] Congress's detailed prescriptions for resolving patent disputes were a key part of the overall compromise.

[4] *See Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 183 (2009) (*Biosimilars Hearing*) (statement of Jack W.

Patent laws reflect Congress's careful balancing of incentives, and "[w]here it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess." *Bonito Boats*, 489 U.S. at 152; *see, e.g.*, *BIO*, 496 F.3d at 1374 (holding preempted drug-price law that attempted "to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs"). States cannot tinker with "congressional calibration" by providing remedies Congress withheld. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 380 (2000); *see Arizona*, 567 U.S. at 406 (state law "attempt[ing] to achieve one of the same goals as federal law," but through a different "method of enforcement," was preempted because it "would interfere with the careful balance struck by Congress"). Because Amgen's state-law claims would second-guess Congress's decisionmaking and upset the BPCIA's balanced approach, they are preempted.

B. Litigating BPCIA Compliance Under 50 Sets Of State Rules Would Frustrate The Purposes And Objectives Of The Streamlined Patent Resolution Process Congress Created.

State law remedies are furthermore preempted because litigating BPCIA compliance under 50 sets of state rules would frustrate the specific purposes and objectives of the statute's patent-litigation provisions: to "establish[] a simple, streamlined patent resolution process." *Biosimilars Hearing*, *supra* note 4, at 9

Lasersohn on behalf of National Venture Capital Association) ("[U]ncertainty . . . actually affects our investment decisions, venture capital investment decisions").

(statement of Rep. Eshoo). Rather than promote a "streamlined" process, adding 50 different state-law glosses onto the federal statute would turn the procedure for resolving patent disputes into a chaotic and uncertain undertaking.

First, it would require biosimilar developers (often relatively small companies that lack the resources of large brand-name drug manufacturers) to master the laws and rules of 50 States and would require courts to determine, in every case, which State's, or States', laws apply. *See Rabe v. United Air Lines, Inc.*, 636 F.3d 866, 871 (7th Cir. 2011) (choice-of-law disputes can be "prolonged and expensive"). And the desire to shop for favorable state law will influence the choice of forum, leading to collateral disputes over personal jurisdiction and venue.

Second, these state-law claims would potentially be litigated separately from patent infringement, and perhaps even beyond this Court's jurisdiction. "Piecemeal litigation is . . . disfavored as a matter of national policy," *Gen. Elec. Co. v. ITC*, 692 F.3d 1218, 1220 (Fed. Cir. 2012), yet that is exactly what would result here. While the patent litigation proceeds in federal court, state-law litigation like the claim Amgen presses here could conceivably be filed in *state* court, *see Gunn v. Minton*, 568 U.S. 251, 257-58 (2013) (discussing the limits of exclusive federal jurisdiction over patent cases), or in a venue not available for patent litigation. *Compare* 28 U.S.C. § 1400(b) (venue for patent infringement) *with id.* § 1391(b), (c)(2) (venue for diversity cases). Removal to federal court might not be available,

see, e.g., 28 U.S.C. § 1441(b)(2), and if removal were based on some ground other than patent "arising under" jurisdiction, the appeal would not go to this Court. *See* 28 U.S.C. § 1295(a)(1). This fragmentation would be an odd result indeed for an area of law—patent litigation—that is intended to be under the exclusive supervision of a single, *federal* appeals court, and for a specific type of patent litigation that is intended to be "simple" and "streamlined."

Third, this scenario could result in a patchwork of injunctions and damages awards based on 50 different state laws. This Court has already held that nation-wide injunctions are not permitted for state-law unfair-competition suits. *See Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1358-60 (Fed. Cir. 2013). Allowing States to use their varying laws (and remedies) to enforce particular BPCIA provisions thus poses a very real possibility of different outcomes, and thus different launch dates, in cases governed by different States' laws. Not only would the state-law judgments themselves be substantively contrary to federal law, but the resulting state-by-state patchwork quilt would be unworkable for biosimilar manufacturers attempting to launch their products *as permitted under federal law*.

Finally, a claim like Amgen's could be brought only after FDA review of a biosimilar has begun, *see* 42 U.S.C. § 262(*l*)(2), and might not be brought until notice of commercial marketing is served. Thus, these collateral disputes could be used to keep a biosimilar off the market, forced to go through the patent dance,

even after FDA licensure *and* expiration or invalidation of all patents. And history plainly shows that brand-name manufacturers will exploit every conceivable avenue to delay generic approval and launch. *See, e.g.*, 153 Cong. Rec. S11938 (daily ed. Sept. 21, 2007) (remarks of Sen. Kennedy).

All of these complications will result in significant litigation costs and uncertainty about launch dates and patient access to cost-effective biologic alternatives, contrary to Congress's clear purpose: to decrease drug prices by introducing biosimilar competition. Uncertainty dampens companies' incentives to invest in biosimilars. Congress enacted a highly reticulated, carefully calibrated statute precisely to minimize this uncertainty, inefficiency, and litigation cost,[5] but Amgen's position would heighten all three. Layering on up to 50 States' remedies would frustrate Congress's purpose and objective to create a *single*, uniform procedure for resolving patent disputes over biosimilars. That procedure is set out in the BPCIA, and any state-law attempt to add to it is preempted.

CONCLUSION

If this Court addresses preemption, it should hold that Amgen's state-law claims are preempted by the BPCIA and affirm judgment in Sandoz's favor.

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[5] *See Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1063 (Fed. Cir. 2016) (legislative history "confirms" Congress's goal in reducing patent litigation uncertainty); *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, 210 F. Supp. 3d 244, 246 (D. Mass. 2016) (the BPCIA's expedited patent resolution procedure "is intended to reduce uncertainty and thus encourage the sale of non-infringing, more affordable biosimilars which may be important to human health").

Respectfully submitted,

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September 5, 2017

CERTIFICATE OF COMPLIANCE

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

Dated: September 5, 2017

/s/ William M. Jay
William M. Jay

CERTIFICATE OF SERVICE

I hereby certify that on September 5, 2017, I electronically filed the foregoing document using the Court's CM/ECF system, which will send notice of such filing to counsel for all parties.

/s/ William M. Jay
William M. Jay