United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,
Plaintiffs-Appellants

v.

SANDOZ INC.,
Defendant-Appellee

2015-1499

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

Decided: December 14, 2017

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Before NEWMAN, LOURIE, and CHEN, *Circuit Judges.*

LOURIE, *Circuit Judge*.

This appeal has returned to us on remand from the Supreme Court of the United States. In their earlier appearance in this court, Amgen Inc. and Amgen Manufacturing Ltd. (collectively, "Amgen") appealed from the decision of the United States District Court for the Northern District of California (1) granting partial judgment on the pleadings to Sandoz Inc. ("Sandoz") on its counterclaims seeking a declaratory judgment interpreting the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010) (codified as amended at 42 U.S.C. § 262, 35 U.S.C. § 271(e), 28 U.S.C. § 2201(b), 21 U.S.C. § 355 et seq.); (2) dismissing with prejudice Amgen's unfair competition claims asserting unlawful business practices under California Business & Professions Code § 17200 et seq. ("UCL") and conversion claims (collectively, the "state law claims"); and (3) denying Amgen's motion for a preliminary injunction based on its state law claims. *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741, 2015 WL 1264756 (N.D. Cal. Mar. 19, 2015) ("*Opinion*").

Following full briefing and oral argument, we affirmed the dismissal of Amgen's state law claims, vacated the judgment on Sandoz's counterclaims, directed the district court to enter judgment on those counterclaims consistent with our opinion, and remanded for further

proceedings. *See Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015), *rev'd in part, vacated in part*, 137 S. Ct. 1664 (2017).

In particular, we held that under 42 U.S.C. § 262(*l*)(8)(A) "a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product." *Id.* at 1357. In addition, we held that the "shall" provision in paragraph (*l*)(2)(A) did not mean "must" and concluded that "when a subsection (k) applicant fails the disclosure requirement [of § 262(*l*)(8)(A)], 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e) expressly provide the only remedies as those being based on a claim of patent infringement." *Id.* at 1355–57.

Both parties petitioned for rehearing en banc, which this court denied. *See Amgen Inc. v. Sandoz Inc.*, No. 15-1499, slip op. (Fed. Cir. Oct. 16, 2015). Sandoz then filed a petition for a writ of certiorari in the Supreme Court presenting the following questions: "Whether notice of commercial marketing given before FDA approval can be effective and whether, in any event, treating Section 262(*l*)(8)(A) as a standalone requirement and creating an injunctive remedy that delays all biosimilars by 180 days after approval is improper." Petition for a Writ of Certiorari at ii, *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017) (No. 15-1039).

Amgen subsequently filed a conditional cross-petition for a writ of certiorari presenting the following questions:

> Is an Applicant required by 42 U.S.C. § 262(*l*)(2)(A) to provide the Sponsor with a copy of its biologics license application and related manufacturing information, which the statute says the Applicant "shall provide," and, where an Applicant fails to provide that required information, is the Sponsor's sole recourse to commence a declaratory-judgment action under 42 U.S.C.

> § 262(*l*)(9)(C) and/or a patent-infringement action under 35 U.S.C. § 27l(e)(2)(C)(ii)?

Conditional Cross-Petition for a Writ of Certiorari at ii, *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017) (No. 15-1195). The Supreme Court granted both Sandoz's petition and Amgen's conditional cross-petition and consolidated the cases for briefing and oral argument. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 808 (2017). The United States filed a brief and argued as amicus curiae.

On June 12, 2017, the Court announced its decision. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017). The Court held that an injunction under federal law is not available to enforce 42 U.S.C. § 262(*l*)(2)(A); and a biosimilar applicant may provide the notice required by 42 U.S.C. § 262(*l*)(8)(A) either before or after receiving FDA approval, *i.e.*, the applicant need not defer giving notice of commercial marketing until FDA licensure of the biosimilar in order to begin the running of the 180-day clock. *Id.* at 1674, 1677. The Court reversed our decision in part and vacated it in part and remanded the case for further proceedings consistent with its opinion. The Court directed:

> On remand, the Federal Circuit should determine whether California law would treat noncompliance with § 262(*l*)(2)(A) as "unlawful." If the answer is yes, then the court should proceed to determine whether the BPCIA pre-empts any additional remedy available under state law for an applicant's failure to comply with § 262(*l*)(2)(A) (and whether Sandoz has forfeited any pre-emption defense, see 794 F.3d, at 1360, n. 5). The court is also of course free to address the pre-emption question first by assuming that a remedy under state law exists.

Id. at 1676–77.

Following remand, we recalled our mandate, reopened the appeal, and directed supplemental briefing on July 26, 2017. Both parties responded with supplemental briefing, which, *inter alia*, addressed the question whether Sandoz waived any preemption defense it had to Amgen's state law claims.

Because Sandoz did not forfeit its preemption defense and the BPCIA preempts state law remedies for an applicant's failure to comply with § 262(*l*)(2)(A), we now affirm the district court's dismissal of Amgen's state law claims.

BACKGROUND

In 2010, as part of the Patient Protection and Affordable Care Act, Congress enacted the BPCIA, which established an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved product ("reference product"). Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. at 815. Congress established such "a biosimilars pathway balancing innovation and consumer interests." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804.

The BPCIA has certain similarities in its goals and procedures to the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984), but it has several obvious differences. We note this as a matter of historical interest, but otherwise do not comment on those similarities and differences.

Under the governing statutory scheme, the Food and Drug Administration ("FDA") approves a biological product for commercial marketing by granting a biologics license under 42 U.S.C. § 262(a). An applicant filing an original biologics license application ("BLA") typically must provide clinical data to demonstrate the safety and efficacy of its product. In contrast, under the abbreviated regulatory approval pathway created by the BPCIA,

codified at 42 U.S.C. § 262(k), an applicant filing an abbreviated biologics license application ("aBLA" or "biosimilar application") instead submits information to demonstrate that its product is "biosimilar" to or "interchangeable" with a previously approved reference product, together with "publicly-available information regarding the [FDA]'s previous determination that the reference product is safe, pure, and potent." *Id.* § 262(k)(2)–(5); *see also id.* § 262(i). The BPCIA thus permits a biosimilar applicant to rely in part on the approved license of a reference product.

To balance the goals of innovation and price competition, Congress enacted the BPCIA to provide a four-year and a twelve-year exclusivity period to a reference product, both beginning on the date of first licensure of the reference product. Specifically, a biosimilar application "may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a)," *id.* § 262(k)(7)(B), and approval of a biosimilar application "may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a)," *id.* § 262(k)(7)(A). Thus, a sponsor of an approved reference product (the "reference product sponsor" or "RPS") receives up to twelve years of exclusivity against follow-on products, regardless of patent protection.

The BPCIA established a biosimilar patent dispute resolution regime by amending Titles 28, 35, and 42 of the United States Code. The BPCIA amended the Patent Act to create an artificial "act of infringement," similar to that of 35 U.S.C. § 271(e)(2)(A), and to allow infringement suits to begin based on the filing of a biosimilar application prior to FDA approval and prior to marketing of the biological product. *See* 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6). The BPCIA also established a unique and elaborate process for information exchange between the biosim-

ilar applicant and the RPS in order to help resolve biosimilar patent disputes. *See* 42 U.S.C. § 262(*l*).

Under that process, codified at 42 U.S.C. § 262(*l*), the biosimilar applicant provides the RPS confidential access to its aBLA and to the manufacturing information pertaining to the biosimilar product no later than 20 days after the FDA accepts its application for review. *Id.* § 262(*l*)(1)–(2). The parties may then exchange lists of patents for which they believe a claim of patent infringement could reasonably be asserted by the RPS, as well as their respective positions on infringement, validity, and enforceability of those patents. *Id.* § 262(*l*)(3). Following that exchange period, the parties negotiate to formulate a list of patents ("listed patents") that would be expected to be the subject of an immediate patent infringement action, *id.* § 262(*l*)(4)–(5), and the RPS then may sue the biosimilar applicant within 30 days, *id.* § 262(*l*)(6). The information exchange and negotiation thus contemplate an immediate infringement action brought by the RPS based only on listed patents.

Subsection 262(*l*) also provides that the applicant give notice of commercial marketing to the RPS at least 180 days prior to commercial marketing of its product licensed under subsection (k). The RPS thus has a period of time to seek a preliminary injunction based on patents that the parties initially identified during information exchange, but which were not selected for an immediate infringement action, as well as any newly issued or licensed patents (collectively, "non-listed patents"). *Id.* § 262(*l*)(7)–(8).

Subsection 262(*l*) additionally provides, in paragraph (*l*)(9)(A), that if the applicant discloses the information "required under paragraph (2)(A)," then neither the RPS nor the applicant may bring a declaratory judgment action based on the non-listed patents prior to the date on which the RPS receives the notice of commercial market-

ing under paragraph (*l*)(8)(A). *Id.* § 262(*l*)(9)(A). Paragraphs (*l*)(9)(B) and (*l*)(9)(C), however, permit the RPS, but not the applicant, to seek declaratory relief with respect to infringement, validity, or enforceability of certain patents in the event that the applicant fails to comply with certain provisions of subsection (*l*). *Id.* § 262(*l*)(9)(B)–(C). "The remedy provided by § 262(*l*)(9)(C) excludes all other federal remedies, including injunctive relief," for failure to comply with § 262(*l*)(2)(A). *Sandoz*, 137 S. Ct. at 1675.

Amgen has marketed filgrastim under the brand name Neupogen® ("Neupogen") since 1991. In May 2014, Sandoz filed an aBLA, seeking FDA approval of a biosimilar filgrastim product, for which Neupogen was the reference product. On July 7, 2014, Sandoz received notification from the FDA that it had accepted Sandoz's application for review.

Immediately thereafter, on July 8, 2014, Sandoz notified Amgen that it: had filed the biosimilar application referencing Neupogen; believed that the application would be approved in "Q1/2 of 2015"; and intended to launch its biosimilar product immediately upon FDA approval. J.A. 1472. Later in July, in response to an inquiry from Amgen, Sandoz confirmed that the FDA had accepted its application for review; it informed Amgen that it had "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance" but that Amgen was entitled to sue Sandoz under § 262(*l*)(9)(C) "to require Sandoz to disclose [its] biosimilar application." J.A. 1495–96. Sandoz thus did not disclose its aBLA or its product's manufacturing information to Amgen according to § 262(*l*)(2)(A).

Accordingly, in October 2014, Amgen sued Sandoz in the Northern District of California, asserting claims of (1) unfair competition by engaging in unlawful business practices under the UCL, based on two alleged violations

of the BPCIA; (2) conversion for allegedly wrongful use of Amgen's approved license on Neupogen; and (3) infringement of Amgen's U.S. Patent 6,162,427 ("the '427 patent"), which claims a method of using filgrastim. Amgen alleged that Sandoz violated the BPCIA by failing to disclose the information required under § 262(*l*)(2)(A) and by giving a premature, ineffective, notice of commercial marketing under § 262(*l*)(8)(A) before FDA approval of its biosimilar product. Sandoz counterclaimed for a declaratory judgment that the BPCIA permitted its actions, that Amgen's state law claims were unlawful and/or preempted, and that the '427 patent was invalid and not infringed. Sandoz also asserted in its answer as an affirmative defense preemption of the state law claims by the BPCIA.

In January 2015, the parties filed cross-motions for judgment on the pleadings on Amgen's state law claims and Sandoz's counterclaims regarding its actions under the BPCIA. In February 2015, Amgen also filed a motion for a preliminary injunction to enjoin Sandoz from launching its biosimilar product, Zarxio, after FDA approval, based solely on its state law claims. Also, in February 2015, through discovery, Amgen obtained access to Sandoz's biosimilar application.

On March 19, 2015, the district court granted partial judgment on the pleadings to Sandoz on its counterclaims to the extent that Sandoz's interpretation of the BPCIA statute was consistent with the court's interpretation. Specifically, the district court concluded that: (1) the BPCIA renders permissible a biosimilar applicant's decision not to disclose its aBLA and the manufacturing information to the RPS, subject only to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(C); (2) such a decision alone does not offer a basis for the RPS to obtain injunctive relief, restitution, or damages against the applicant; and (3) the applicant may give notice of commercial

marketing under § 262(*l*)(8)(A) before FDA approval. *Opinion*, 2015 WL 1264756, at *8, *11.

Based on its interpretation of the BPCIA, the district court then dismissed Amgen's unfair competition and conversion claims with prejudice, concluding that Sandoz did not violate the BPCIA or act unlawfully. *Id.* at *8–9. Sandoz did not then argue, and the district court did not address, its preemption counterclaim or affirmative defense. J.A. 1876–77. The court also denied Amgen's motion for a preliminary injunction based on its state law claims, noting that Amgen "has yet to proceed on its remaining claim for patent infringement." *Opinion*, 2015 WL 1264756, at *10.

On the parties' joint motion, on March 25, 2015, the district court entered final judgment as to Amgen's unfair competition and conversion claims and as to Sandoz's BPCIA counterclaims under Rule 54(b) of the Federal Rules of Civil Procedure.

On October 15, 2015, Amgen filed its First Amended and Supplemental Complaint, which added a claim for infringement of Amgen's U.S. Patent 8,940,878 ("the '878 patent"). On September 13, 2017, the district court entered a stipulated judgment of noninfringement of the '427 patent. The parties' claims and counterclaims relating to infringement, validity, and enforceability of the '878 patent remain pending at the district court.

Meanwhile, on March 6, 2015, the FDA approved Sandoz's aBLA for all approved uses of Amgen's Neupogen. Although Sandoz did not launch its filgrastim product at that time, it eventually did so after our decision on appeal.

Amgen timely appealed from the March 25, 2015 final judgment as to Amgen's unfair competition and conversion claims and as to Sandoz's BPCIA counterclaims, and from the denial of a preliminary injunction. We have

jurisdiction under 28 U.S.C. § 1295(a)(1) and § 1292(a)(1) and (c)(1).

DISCUSSION

We apply the procedural law of the regional circuit, here the Ninth Circuit, when reviewing a district court's grant of a motion for judgment on the pleadings. *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1320 (Fed. Cir. 2007). The Ninth Circuit reviews the grant of judgment on the pleadings *de novo*, *Peterson v. California*, 604 F.3d 1166, 1169 (9th Cir. 2010), and "accept[s] all material allegations in the complaint as true and construe[s] them in the light most favorable to [the non-moving party]," *Turner v. Cook*, 362 F.3d 1219, 1225 (9th Cir. 2004) (third alteration in original).

Amgen argues that (1) Sandoz waived its preemption defense to its state law claims in this appeal; (2) the BPCIA does not preempt state law remedies for failure to comply with § 262(*l*)(2)(A); and (3) failure to comply with § 262(*l*)(2)(A) is both "unlawful" under the UCL and an act of conversion. Sandoz responds that (1) we have discretion to address preemption now; (2) both field and conflict preemption bar Amgen's state law claims; (3) Amgen's state law claims fail under California law; and (4) Amgen abandoned its conversion claim. We will address the parties' arguments in turn.[1]

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[1] Because we conclude that Sandoz did not waive its preemption defense and Amgen's state law claims are preempted, we do not reach the parties' arguments relating to (1) whether Sandoz preserved its conversion claims; or (2) whether failure to comply with § 262(*l*)(2)(A) is "unlawful" under the UCL or an act of conversion. *See Sandoz*, 137 S. Ct. at 1677 ("The court is also of course free to address the pre-emption question first by assuming that a remedy under state law exists.").

I.

We first address the parties' waiver arguments. "Under the usual rule, an affirmative defense is deemed waived if it has not been raised in a pleading, by motion, or at trial." *Daingerfield Island Protective Soc'y v. Babbitt*, 40 F.3d 442, 445 (D.C. Cir. 1994) (internal quotation marks omitted); *see also* Fed. R. Civ. P. 12(h)(2) (listing "[f]ailure to state a claim upon which relief can be granted" as a defense that may be raised "in any pleading allowed or ordered under Rule 7(a)"; "by a motion under Rule 12(c)"; or "at trial").

Neither the district court nor this court in its prior decision addressed preemption on the merits. The Supreme Court has observed that as a "general rule . . . a federal appellate court does not consider an issue not passed upon below." *Singleton v. Wulff*, 428 U.S. 106, 120 (1976). Appellate courts, however, have discretion to decide when to deviate from this general waiver rule. *See id.* at 121 ("The matter of what questions may be taken up and resolved for the first time on appeal is one left primarily to the discretion of the courts of appeals, to be exercised on the facts of individual cases."). We have previously articulated five reasons that may justify an appellate court's consideration of an issue not argued to the district court:

> (i) the issue involves a pure question of law and refusal to consider it would result in a miscarriage of justice; (ii) the proper resolution is beyond any doubt; (iii) the appellant had no opportunity to raise the objection at the district court level; (iv) the issue presents significant questions of general impact or of great public concern; or (v) the interest of substantial justice is at stake.

L.E.A. Dynatech, Inc. v. Allina, 49 F.3d 1527, 1531 (Fed. Cir. 1995) (internal quotation marks and alteration omitted); *see also Interactive Gift Express, Inc. v. Com-*

puserve Inc., 256 F.3d 1323, 1344–45 (Fed. Cir. 2001) (citing *L.E.A.*, 49 F.3d at 1531). We consider subcategory iv especially compelling here. The issue of preemption is a significant question regarding the interpretation of the BPCIA.

Amgen argues that Sandoz waived its preemption defense by not arguing it before the district court. According to Amgen, "preemption is an affirmative defense that can be waived." Appellants' Suppl. Br. 8 (citing *Teutscher v. Woodson*, 835 F.3d 936, 945 n.1 (9th Cir. 2016); *Russian Media Grp., LLC v. Cable Am. Inc.*, 598 F.3d 302, 309 (7th Cir. 2010); *Wood v. Milyard*, 566 U.S. 463, 470 (2012)). Amgen stresses that we previously declined to address preemption in this case. Amgen further contends that we should not remand the issue of preemption to the district court.

Sandoz responds that we have discretion to address its preemption defense now. Sandoz contends that "this is a case of great importance" and "preemption will have been 'fully briefed' and is a pure 'matter of law.'" Appellee's Suppl. Br. 8 (quoting *Interactive Gift*, 256 F.3d at 1345). Sandoz further argues that Amgen will not be prejudiced by our consideration of preemption because Sandoz can assert preemption in the district court later as it preserved the defense in its answer.

We agree with Sandoz that we have discretion to address preemption in this appeal and should exercise that discretion. The Supreme Court expressly invited us to do so, and to assume that a remedy under state law would exist if there were not preemption. *See Sandoz*, 137 S. Ct. at 1676–77. We hereby make that assumption.

Preemption is a legal question that the parties have fully briefed. This appeal, and its remand, require us to consider whether state law claims may play a role in enforcing compliance with § 262(*l*)(2)(A). Preemption in this case thus presents "a significant question[] of general

impact or of great public concern." *See Hall v. Bed Bath & Beyond, Inc.*, 705 F.3d 1357, 1371 (Fed. Cir. 2013) (holding party did not waive preemption argument by failing to raise it in its Rule 12(b)(6) motion because "waiver is generally inapplicable to 'significant questions of general impact or of great public concern.'" (quoting *Interactive Gift*, 256 F.3d at 1345)).

Moreover, even if we declined to reach preemption now, Sandoz could raise the defense on remand before the district court. Sandoz preserved its ability to assert preemption by pleading the defense in its answer. *See Daingerfield*, 40 F.3d at 445 (holding defense pled in answer not waived even though defendant failed to assert the defense before the prior appeal); 5 C. Wright & A. Miller, Federal Practice and Procedure § 1277 (3d ed. 2017) (explaining "the failure to raise an affirmative defense by motion will not result in a waiver as long as it is interposed in the answer"); *see also* Fed. R. Civ. P. 12(h)(2). We thus discern no prejudice to Amgen by resolving the preemption issue now.

Amgen's cited cases are readily distinguishable. In *Teutscher*, the Ninth Circuit "decline[d] to consider [preemption] sua sponte." 835 F.3d at 945 n.1. Here, preemption has been fully briefed and the Supreme Court expressly invited us to address the issue on remand. *See Sandoz*, 137 S. Ct. at 1676–77.

In *Russian Media*, the Seventh Circuit declined to address preemption for the first time on appeal in reviewing a district court's grant of a preliminary injunction where preemption had not been timely raised at the district court. *See* 598 F.3d at 309 ("It is not appropriate for this court to overturn an injunction on the basis of a defense that the district court had no opportunity to consider."). The court "express[ed] no opinion on whether the preemption defense is preserved for further proceedings in the district court." *Id.* Here, we are not reviewing the grant

of a preliminary injunction and Sandoz timely raised the defense in its answer.

In *Wood*, the Supreme Court stated the general rule that "[a]n affirmative defense, once forfeited, is excluded from the case, and, as a rule, cannot be asserted on appeal," 566 U.S. at 470 (internal citations and alternations omitted), and went on to recognize an exception to that general rule in the case, *id.* at 473. Here, we have determined that Sandoz has not forfeited its preemption defense, so the general rule has no applicability.

II.

We therefore turn to the question whether Amgen's state law claims are preempted by the BPCIA. We apply our own law to determine whether the BPCIA preempts the state law claims. *See Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1360–61 (Fed. Cir. 1999) (en banc in relevant part) ("In order to fulfill our obligation of promoting uniformity in the field of patent law, it is equally important to apply our construction of patent law to the questions whether and to what extent patent law preempts or conflicts with other causes of action."), *abrogated on other grounds by TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, 28 (2001). Preemption is a question of law that we review *de novo*. *Ultra-Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1376 (Fed. Cir. 2005).

A.

The Supremacy Clause states a clear rule that federal law "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. The Supremacy Clause preempts state law by means of express preemption, field preemption, or conflict preemption. *See English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79 (1990). "Pre-

emption fundamentally is a question of congressional intent and when Congress has made its intent known through explicit statutory language, the courts' task is an easy one." *Id.* (internal citation omitted). Express preemption is not at issue in this appeal, so we focus only on the latter two forms of preemption.

Under field preemption, "state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *Id.* at 79. We may infer such a congressional intent from a "scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," or where an Act of Congress "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). "Where Congress occupies an entire field . . . even complementary state regulation is impermissible." *Arizona v. United States*, 567 U.S. 387, 401 (2012).

State laws are also preempted when they conflict with federal law. *Id.* at 399. Conflict preemption occurs "where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *English*, 496 U.S. at 79 (internal citation and quotation marks omitted).

Additionally, where Congress has legislated "in [a] field which the States have traditionally occupied," "we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice*, 331 U.S. at 230. No such "presumption against finding federal pre-emption of a state law cause of action" applies, however, where the field is not "'a field

which the States have traditionally occupied.'" *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001) (quoting *Rice*, 331 U.S. at 230). We conclude that both field and conflict preemption exist here.

B.

Amgen argues that the BPCIA does not preempt state law remedies for failure to comply with § 262(*l*)(2)(A). Amgen contends that we have "held that patent law does not fully preempt related state-law doctrines," including "state unfair-competition laws." Appellants' Suppl. Br. 15 (citing *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1333 (Fed. Cir. 1998), *overruled on other grounds by Midwest Indus.*, 175 F.3d 1356). According to Amgen, field preemption does not apply to its state law claims because "the federal statute does not provide a meaningful remedy for the state-recognized interests that have been injured by Sandoz's failure to comply with 42 U.S.C. § 262(*l*)(2)(A)." *Id.* at 16.

Sandoz responds that field preemption bars Amgen's state law claims because the BPCIA's comprehensive framework demonstrates Congressional intent that federal law exclusively occupy the field of patent dispute resolution triggered by the filing of a biosimilar application. According to Sandoz, the inference of Congressional intent to occupy the field is particularly strong because the scheme "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." Appellee's Suppl. Br. 12 (alternation in original) (quoting *Rice*, 331 U.S. at 230). Sandoz also contends that no presumption against preemption applies here.

We agree with Sandoz that the BPCIA preempts state law claims predicated on an applicant's failure to comply with § 262(*l*)(2)(A). As an initial matter, no presumption against preemption applies in this case because biosimilar patent litigation "is hardly 'a field which the States have

traditionally occupied.'" *Buckman*, 531 U.S. at 347 (quoting *Rice*, 331 U.S. at 230). Indeed, patents are "inherently federal in character" because a patent "originates from, is governed by, and terminates according to federal law." *Id.* In keeping with this federal character, Congress has granted federal courts "exclusive jurisdiction over cases 'arising under any Act of Congress relating to patents.'" *Gunn v. Minton*, 568 U.S. 251, 253 (2013) (quoting 28 U.S.C. § 1338(a)); *see also* 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, plant variety protection, or copyrights."). Similarly, the FDA has exclusive authority to license biosimilars pursuant to the provisions of 42 U.S.C. § 262. *See* 42 U.S.C. § 262(a)(1).

The BPCIA is a "complex statutory scheme . . . [that] establishes processes both for obtaining FDA approval of biosimilars and for resolving patent disputes between manufacturers of licensed biologics and manufacturers of biosimilars." *Sandoz*, 137 S. Ct. at 1669. It "sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of [patent] infringement." *Id.* at 1670 (citing 42 U.S.C. § 262(*l*)). Congress established this scheme as part of its careful "balancing [of] innovation and consumer interests." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804.

Similar to the federal alien registration system in *Arizona* that the Supreme Court held preempted that field, the scheme here is "comprehensive" and "provide[s] a full set of standards governing" the exchange of information in biosimilar patent litigation, "including the punishment for noncompliance." *Arizona*, 567 U.S. at 401. The Supreme Court has held that "[t]he remedy provided by § 262(*l*)(9)(C) excludes all other federal remedies, including injunctive relief," for failure to comply with § 262(*l*)(2)(A). *Sandoz*, 137 S. Ct. at 1675. The Court has described the BPCIA as possessing a "carefully crafted

and detailed enforcement scheme" and stated that this scheme "provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly." *Id.* at 1675 (emphasis in original) (internal quotations omitted). The BPCIA's comprehensive, carefully calibrated "scheme of federal regulation . . . [is] so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Rice*, 331 U.S. at 230.

Moreover, Amgen seeks through California law to impose penalties on Sandoz for failure to comply with § 262(*l*)(2)(A), *e.g.*, injunctive relief and damages, that the BPCIA does not provide. Section 262(*l*)(9)(C) permits the RPS, but not the applicant, to bring an action "for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product." Because § 262(*l*)(9)(C) provides the exclusive federal remedy for failure to comply with § 262(*l*)(2)(A), federal law does not permit injunctive relief or damages for such failure. *See Sandoz*, 137 S. Ct. at 1675. "Permitting the State to impose its own penalties for the [alleged violation of federal law] here would conflict with the careful framework Congress adopted." *Arizona*, 567 U.S. at 402; *cf. Amalgamated Ass'n of St., Elec. Ry. & Motor Coach Emps. of Am. v. Lockridge*, 403 U.S. 274, 287 (1971) (holding state law claim preempted and explaining "[t]he technique of administration and the range and nature of those remedies that are and are not available is a fundamental part and parcel of the operative legal system established by the [preempting] Act"). This conflict in available remedies between federal and state law "underscore[s] the reason for field preemption." *Arizona*, 567 U.S. at 403.

Amgen's reliance on *Hunter Douglas* is misplaced. In *Hunter Douglas*, we held that "federal patent law" did not preempt "the field pertaining to state unfair competition law." 153 F.3d at 1333. But our recognition that patent

law does not preempt all related state law claims does not dictate the outcome in this case. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 154, 167 (1989) (stating that "all state regulation of potentially patentable but unpatented subject matter is not *ipso facto* preempted by the federal patent laws" and holding preempted the particular state law at issue, which "enter[ed] a field of regulation which the patent laws have reserved to Congress"). The field here is biosimilar patent litigation, not patent law generally. As explained above, the federal government has fully occupied this field.

Additionally, Amgen's assertion that the BPCIA "does not provide a meaningful remedy for the state-recognized interests that have been injured by Sandoz's failure to comply with 42 U.S.C. § 262(*l*)(2)(A)," Appellants' Suppl. Br. 16, misunderstands the relevant inquiry. The Supreme Court has explained that "[p]re-emption fundamentally is a question of congressional intent," *English*, 496 U.S. at 78–79, and reiterated that "'[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (alternation in original) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). As discussed *supra*, this "scheme of federal regulation . . . [is] so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Rice*, 331 U.S. at 230. Thus, assuming *arguendo* that there are any state-recognized interests in play here, California law must "give way to federal law." *See Arizona*, 567 U.S. at 399.

C.

Amgen also argues that the BPCIA does not conflict with Amgen's state law claims. First, Amgen contends, the state law claims "do not 'clash' with the objectives of the BPCIA and federal patent laws." Appellants' Suppl. Br. 12 (quoting *Sears, Roebuck & Co. v. Stiffel Co.*, 376

U.S. 225, 231 (1964)). Second, according to Amgen, the state law claims include additional elements not addressed by the BPCIA or found in the patent litigation facilitated by the BPCIA. *See Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1306 (Fed. Cir. 1999). Third, Amgen argues that the state law claims do not depend on the resolution of Amgen's patent disputes and that the relief sought is both different from and independent of the remedy provided by the BPCIA and patent law.

Sandoz responds that the state law remedies conflict with the intricate federal scheme. According to Sandoz, such remedies "would disrupt the balance struck by the BPCIA's express consequences for noncompliance with its procedural steps," Appellee's Suppl. Br. 13, frustrating "Congress's deliberate omission of an injunction to compel disclosure of an application, and its provision of only the Section 262(*l*)(9)(C) consequence," *id.* at 14. Sandoz contends that this "disruption to the federal scheme would be compounded by the multiplicity of remedies different states might make available for 'violations' of the BPCIA." *Id.* at 15–16.

We agree with Sandoz that conflict preemption also bars Amgen's state law claims. Contrary to Amgen's assertions, its state law claims "clash" with the BPCIA, and the differences in remedies between the federal scheme and state law claims support concluding that those claims are preempted. As the Supreme Court has recognized, a "[c]onflict in technique can be fully as disruptive to the system Congress erected as conflict in overt policy." *Amalgamated Ass'n*, 403 U.S. at 287. Additionally, compliance with the BPCIA's "detailed regulatory regime in the shadow of 50 States' tort regimes," and unfair competition standards, could "dramatically increase the burdens" on biosimilar applicants beyond those contemplated by Congress in enacting the BPCIA. *Buckman*, 531 U.S. at 350.

As previously discussed, Amgen seeks through state law to impose penalties on Sandoz unavailable under the BPCIA for failure to comply with § 262(*l*)(2)(A)'s disclosure requirements. This "conflict in the method of enforcement" between the BPCIA and state law creates "an obstacle to the regulatory system Congress chose." *Arizona*, 567 U.S. at 406. We must assume that Congress acted intentionally when it did not provide an injunctive remedy for breach of § 262(*l*)(2)(A)'s disclosure requirements. *See Sandoz*, 137 S. Ct. at 1675. Where, as here, "Congress made a deliberate choice not to impose" certain penalties for noncompliance with federal law, state laws imposing those penalties "would interfere with the careful balance struck by Congress." *Arizona*, 567 U.S. at 405–06.

Amgen's reliance on *Rodime* is misplaced. In *Rodime*, we determined that the patent laws did not preempt patentee's state law claims for tortious interference with prospective economic advantage and unfair competition based on the accused infringer's alleged efforts to dissuade other companies from taking a license to the asserted patent. 174 F.3d at 1306. Our statement, applied to the facts of *Rodime*, that "[t]he patent laws will not preempt such claims if they include additional elements not found in the federal patent law cause of action and if they are not an impermissible attempt to offer patent-like protection to subject matter addressed by federal law," *id.*, does not immunize state law claims in other types of cases from ordinary principles of preemption. As discussed *supra*, the preemption analysis here demonstrates that Amgen's state law claims conflict with the BPCIA and intrude upon a field, biosimilar patent litigation, that Congress reserved for the federal government.

We have considered Amgen's remaining arguments but find them to be unpersuasive.

CONCLUSION

For the foregoing reasons, we affirm the dismissal of Amgen's unfair competition and conversion claims. Amgen's state law claims are preempted on both field and conflict grounds.

AFFIRMED

COSTS

Each party shall bear its own costs.