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, Judge Richard Seeborg

SUPPLEMENTAL BRIEF FOR DEFENDANT-APPELLEE SANDOZ INC.

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CERTIFICATE OF INTEREST

Counsel for defendant-appellee Sandoz Inc. certifies the following:

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

Sandoz Inc.

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 parent corporations and any publicly held companies that own 10% or more of the stock of the party or amicus curiae represented by me are:

Sandoz Inc. is an indirect subsidiary of Novartis AG, which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

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 are expected to appear in this court are:

Morrison & Foerster LLP: Rachel Krevans, David C. Doyle, Deanne E. Maynard, Grant J. Esposito, Anders T. Aannestad, Erik J. Olson, Marc A. Hearron, Stephen D. Keane, Joseph R. Palmore, Julie Y. Park, Bryan J. Leitch, Lena H. Hughes, Brian M. Kramer, Eric C. Pai, Jessica A. Roberts. Kirkland & Ellis LLP: James F. Hurst, Michael D. Shumsky, John K. Crisham, Reid P. Huefner, James W. Beard.

Dated: August 28, 2017 /s/ Deanne E. Maynard

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INTRODUCTION

Sandoz responds to this Court's Order requesting its position on the appropriate action to be taken on remand from the Supreme Court.

If this Court decides to address the remanded issues now, it should affirm the dismissal of Amgen's state law claims. Those claims are preempted by the highly reticulated Biologics Price Competition and Innovation Act (BPCIA). Allowing the 50 states to overlay their own disparate remedies onto the BPCIA's complex procedural scheme would disrupt the careful balance struck by Congress. As the Supreme Court recognized, Congress chose which remedies to provide and chose not to provide others.

Even were Amgen's claims not preempted, they fail on the merits. To state a claim under the "unlawful" prong of California's Unfair Competition Law (UCL), some other statute (here, the BPCIA) must affirmatively make the conduct unlawful. But as the Supreme Court explained, failure to disclose a biosimilar application is neither lawful nor unlawful under federal law. That defeats Amgen's UCL claim. And Amgen has abandoned its conversion claim, which fails in any event, as this Court already concluded.

In the alternative, Sandoz renews its request (ECF174) for an immediate remand to the district court, so that the district court can address the remanded issues in the first instance along with other claims it already is addressing.

BACKGROUND

Sandoz's biosimilar. In 2014, the FDA accepted Sandoz's application for a biosimilar of filgrastim, a biologic Amgen had long marketed as Neupogen. 794 F.3d 1347, 1352 (Fed. Cir. 2015). Sandoz then informed Amgen that it intended to market its biosimilar upon approval and that it had "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance," thus permitting Amgen to bring a declaratory judgment action for patent infringement. A1495-A1497 (citing 42 U.S.C. § 262(*l*)(9)(C)).

Initial district court proceedings. Later in 2014, Amgen sued Sandoz, asserting a UCL claim solely under the "unlawful" prong, which provides a cause of action for "any unlawful … business act or practice." 794 F.3d at 1353, 1360. Amgen alleged that Sandoz violated the BPCIA (1) by not providing Amgen with Sandoz's application within 20 days of FDA's acceptance and (2) by giving notice of commercial marketing before approval. *Id.* at 1353. Amgen also asserted a conversion claim for allegedly wrongful use of Amgen's approved Neupogen license. *Id.* And, expressly invoking 35 U.S.C. § 271(e)(2)(C)(ii) of the BPCIA, and no other basis, Amgen sued for artificial patent infringement. *Id.*; A79.

Sandoz's answer asserted twelve affirmative defenses, including that federal law preempts Amgen's state law claims. A275-A276. Sandoz also asserted BPCIA-related counterclaims for declaratory judgments. A282-A285.

Amgen moved and Sandoz cross-moved for judgment on the pleadings on Amgen's state law claims and Sandoz's BPCIA counterclaims. In that preliminary motion asserting that Amgen's affirmative case failed (A351-A379), Sandoz did not press its affirmative defenses, such as preemption. The district court granted Sandoz's motion (A1-A19) and entered a partial final judgment. 794 F.3d at 1353-54. The district court thus has not yet addressed preemption. *Id.* at 1360 n.5.

Proceedings in this Court. This Court affirmed the dismissal of Amgen's state law claims, vacated the judgment on Sandoz's counterclaims, and remanded. 794 F.3d at 1351. The Court held that "[b]ecause Sandoz took a path expressly contemplated by the BPCIA, it did not violate the BPCIA by not disclosing its [application] and the manufacturing information by the statutory deadline." *Id.* at 1357. The Court also interpreted the notice of commercial marketing provision to mean that the "applicant may only give effective notice of commercial marketing after the FDA has licensed its product." *Id.*

Supreme Court proceedings. The Supreme Court vacated in part and reversed in part, and remanded. 137 S. Ct. 1664, 1678 (2017). The Court held that a biosimilar "applicant may provide notice [of commercial marketing] either before or after receiving FDA approval." *Id.* at 1677. The Court also addressed "whether § 262(*l*)(2)(A)'s requirement that an applicant provide the sponsor with its application and manufacturing information is enforceable by an injunction

under either federal or state law." *Id.* at 1674. It answered no to the first question: "an injunction under federal law is not available to enforce § 262(*l*)(2)(A)." *Id.*

The Supreme Court then considered whether a state law remedy might be available for Sandoz's decision not to provide its application. The Supreme Court observed that this Court had "rejected Amgen's request for an injunction under state law for two reasons." *Id.* at 1676. First, this Court had noted that "California's unfair competition law [does not] provide a remedy when the underlying statute specifies an 'expressly . . . exclusive' remedy." *Id.* (quoting 794 F.3d at 1360; omission by Supreme Court). This Court had "held that [35 U.S.C.] § 271(e)(4), by its text, 'provides the "only remedies"'" for non-disclosure of its application. *Id.* The Supreme Court disagreed with this interpretation, concluding that "[b]ecause § 271(e)(4) provides remedies only for artificial infringement, it provides no remedy at all, much less an 'expressly . . . exclusive' one," for failure to provide a biosimilar application. *Id.* (omission by Supreme Court).

Second, the Supreme Court observed that this Court had rejected Amgen's UCL claim on the ground that non-disclosure "does not violate the BPCIA" and thus cannot be "'unlawful' under California's unfair competition law." *Id.* The Court concluded that the "BPCIA, standing alone, does not require a court to decide whether § 262(l)(2)(A) is mandatory or conditional"—that was not a "question of federal law." *Id.* Instead, all that mattered for purposes of federal law

was the consequence of failure to disclose the application, which was authorization for "an immediate declaratory-judgment action pursuant to § 262(*l*)(9)(C)." *Id.*

The Supreme Court thus remanded for consideration of "whether California law would treat noncompliance with § 262(*l*)(2)(A) as 'unlawful.'" *Id.* "If the answer is yes," the Supreme Court instructed, the question would be "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)." *Id.* at 1676-77 (citing 794 F.3d at 1360 n.5). As explained below (*infra* Part III.B), the Supreme Court did not address Amgen's conversion claim, which Amgen has abandoned.

***Ongoing proceedings*.** After this Court's 2015 mandate, the district court resumed proceedings on Amgen's patent claims. Fact discovery closed in June 2017, initial expert reports were exchanged in July, summary judgment motions are due in October, and trial is set for March 2018. N.D. Cal. ECF248, 253.

ARGUMENT

I. THE CASE SHOULD BE REMANDED TO THE DISTRICT COURT

Rather than conducting another separate appellate proceeding on only one part of this case, this Court has discretion to remand to the district court, where the case is being actively litigated. That would allow the California-based district court to address the remaining questions on Amgen's state law claims. Then, if

necessary, this Court could address those questions, along with any issues arising from resolution of Amgen's patent claims, in one appeal after final judgment.[1]

A remand would preserve this Court's role as one of review, rather than first view. And it would allow the district court to first address questions of California law. If this Court remands, Sandoz will ask the district court to align briefing on the remanded issues with the existing schedule for summary judgment. That approach would not prejudice Amgen, which has known about the preemption defense since Sandoz's answer. A1869 (Amgen's counsel: "[W]e very much believe that there is a preemption argument made." (citing Sandoz's answer)).

Remand also would make it unnecessary to address the waiver question flagged by the Supreme Court and this Court's briefing order. 137 S. Ct. at 1676-77; ECF177. As this Court previously noted, Sandoz did not rely on preemption in the motions for judgment that resulted in "*this appeal*." 794 F.3d at 1360 n.5 (emphasis added). But Sandoz preserved the defense by including it in its answer (A6, A275, A285) and made clear it simply had not placed the defense at issue in these preliminary motions. A1877 (Sandoz's counsel to district court:

[1] Although the Supreme Court stated that this Court should decide the remanded questions (137 S. Ct. at 1676), courts of appeals often remand to district courts when the Supreme Court has remanded to them. *E.g.*, *Icon Health & Fitness, Inc. v. Octane Fitness, LLC*, 576 Fed. App'x 1002, 1005 (2014); *Homar v. Gilbert*, 149 F.3d 1164 (3d Cir. 1998) (Table) (following Supreme Court remand of an issue "for consideration by the Court of Appeals," 520 U.S. 924, 936 (1997)).

"[W]e did not move on that counterclaim [discussing preemption]. So it is just not before the Court *right now*. The Court: Right, I understand." (emphasis added)).[2]

The defense thus remains available to Sandoz. "[T]he failure to raise an affirmative defense by motion will not result in a waiver as long as it is interposed in the answer." 5 Charles Alan Wright, et al., Fed. Prac. & Proc. Civ. § 1277 (3d ed. Apr. 2017); *see* Fed. R. Civ. P. 12(h)(2), (i). A defendant is free to move for judgment on only some of its defenses without waiving its right to assert other pleaded defenses later in the case. *E.g.*, *Daingerfield Island Protective Soc'y v. Babbitt*, 40 F.3d 442, 445 (D.C. Cir. 1994) (rejecting argument that defendant had waived statute of limitations defense preserved in its answer by not asserting it in first summary judgment motion); *English v. Dyke*, 23 F.3d 1086, 1089-91 (6th Cir. 1994) (defendant permitted to move for judgment on the pleadings or summary judgment based on defense preserved in answer but not asserted in earlier motion to dismiss). Thus, regardless of whether preemption was preserved for this appeal, Sandoz could still assert it on remand by later motion.

[2] Although Amgen previously asserted in this Court that "Sandoz's counsel abandoned preemption" in district court (ECF92 at 25), that is not so. When the district court asked whether Sandoz was "withdrawing [preemption] from your defense?", Sandoz's counsel replied that "we would have to look at that" and explained the issue was just not briefed in these motions. A1876-A1877. This Court recognized as much in its decision. 794 F.3d at 1360 n.5.

II. AMGEN'S STATE LAW CLAIMS ARE PREEMPTED

If the Court does not remand, it should hold the state law claims preempted by the BPCIA. 137 S. Ct. at 1677 (noting this Court is "of course free to address the pre-emption question first by assuming that a remedy under state law exists").

A. This Court Can Decide Preemption In This Appeal

This Court has discretion to address preemption now, even though it was not argued to or considered by the district court in the motions on appeal. *See Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1344 (Fed. Cir. 2001) (setting forth various factors justifying consideration of an issue for the first time on appeal). If this Court decides to resolve any of the open issues rather than remand, it should exercise its discretion to resolve preemption, for several reasons.

First, as shown by the grant of certiorari, the participation by the United States before the Supreme Court, and the broad amicus involvement, this is a case of great importance to both the public and industry participants. Thus, the need for guidance counsels strongly in favor of resolving all relevant issues. *Id.* at 1345 ("significant questions of general impact or of great public concern" can justify review of issue not pressed below) (quotation omitted). Second, preemption will have been "fully briefed" and is a pure "matter of law." *Id.* Third, given that Sandoz preserved preemption in its answer and can assert it later in any event (*supra* Part I), Amgen would not be prejudiced by this Court's consideration of it

now. *See Interactive Gift Exp.*, 256 F.3d at 1345. Indeed, this Court has previously considered a preemption issue that had not been pressed below. *Hall v. Bed Bath & Beyond, Inc.*, 705 F.3d 1357, 1371 (Fed. Cir. 2013). Finally, this Court has recognized that, upon a Supreme Court remand, "a court of appeals may consider relevant decisions and arguments that were not previously before it to promote fairness." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 590 n.8 (Fed. Cir. 2000) (en banc) (quotation omitted), *vacated on other grounds*, 535 U.S. 722 (2002).[3]

B. Both Field And Conflict Preemption Bar Amgen's Claims

The BPCIA preempts Amgen's state law claims. Preemption need not be express, but instead can be based on a statute's structure and language. *FMC Corp. v. Holliday*, 498 U.S. 52, 56-57 (1990). Under field preemption, state law must give way where it "regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Under conflict preemption, state law is preempted when it "stand[s] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Barnett Bank of Marion Cty. v. Nelson*, 517 U.S. 25, 31

[3] If this Court nevertheless declines to exercise its discretion to reach preemption in this appeal and yet were to conclude that Amgen has stated a state law claim, it should leave the preemption issue open, because Sandoz can still raise preemption in the district court by later motion. *Supra* Part I.

(1996) (citations omitted). Both standards are met here: Amgen seeks nonfederal remedies for an alleged violation of the BPCIA's application-disclosure provision, yet interjecting disparate remedies of 50 states into the BPCIA's complex procedural scheme would replace the remedies explicitly determined by Congress.

As an initial matter, no presumption against preemption applies. Such a presumption applies only where states are regulating in "a field which the States have traditionally occupied." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-48 (2001) (quotation omitted). Here, licensing biosimilars, policing the BPCIA's patent exchange process, and litigating federally granted patent rights are not remotely fields of traditional state regulation. To the contrary, only the FDA has authority to license biosimilars. 42 U.S.C. § 262(a)(1)(A). Additionally, patents are created and governed by federal law (U.S. Const. art. I, § 8, cl. 8); federal courts have exclusive jurisdiction over patent cases (*Gunn v. Minton*, 133 S. Ct. 1059, 1062 (2013)); and the BPCIA's information exchange process determines the timing and scope of the federal infringement suit.

The comprehensive nature of the BPCIA's regulatory regime requires California's law to give way. Congress's intent to occupy a field—and thus to completely displace state regulation—can be inferred 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." *Rice v. Santa Fe Elevator Corp.*, 331

U.S. 218, 230 (1947). For example, in *Arizona v. United States*, the Supreme Court inferred Congressional intent to occupy the field of alien registration from Congress's creation of a comprehensive statutory framework "provid[ing] a full set of standards governing alien registration, including the punishment for noncompliance." 567 U.S. 387, 401 (2012). The federal legislation there "struck a careful balance," detailing when aliens do and do not need to apply for registration, whether they must carry proof of registration, and the penalties for noncompliance. *Id.* at 400-01. State law thus was preempted even though it was complementary to federal law and adopted its substantive standards. *Id.* at 402.

Here, the BPCIA's comprehensive framework demonstrates Congressional intent for federal law exclusively to occupy the field of patent dispute resolution triggered by the filing of a biosimilar application. As the Supreme Court explained, the BPCIA is a "complex statutory scheme" governing both "FDA approval of biosimilars" and resolution of patent disputes. 137 S. Ct. at 1669. In particular, the "BPCIA sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement." *Id.* at 1670. It details the precise procedural steps within the patent dispute resolution regime, and it has a "carefully crafted and detailed enforcement scheme" providing the exact consequences for noncompliance. *Id.* at 1675. Like the alien-registration scheme in *Arizona*, the BPCIA's patent dispute resolution scheme "was designed as a

harmonious whole." 567 U.S. at 401 (quotation omitted). Congress "left no room" for the 50 states to supplement its regime. *Rice*, 331 U.S. at 230.

Inference of Congressional intent to occupy a field is particularly strong where the comprehensive federal 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." *Id.* The patent laws are such an area. The federal government's interest in national uniformity in patent protection and adjudication is so dominant that federal courts have exclusive jurisdiction of actions arising under the patent laws, and this Court was created to provide national uniformity. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989). The Supreme Court has thus made clear that "state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws." *Id.* at 152. Unless preempted, California state law could affect the timing and scope of federal patent litigation under the BPCIA—an area in which Congress left no room for state involvement.

Similarly, under conflict preemption, state law claims may be preempted because of the "comprehensive scheme" at issue and the federal law's own calibrated enforcement tools. *Buckman*, 531 U.S. at 348, 350. In *Buckman*, Congress created a comprehensive scheme that balanced two competing interests: (1) encouraging competition and increasing availability of medical devices and

(2) ensuring the safety of those devices through an appropriate approval process. *Id.* at 348–52. The Court concluded that permitting state law claims to interfere with this process would disrupt the balance struck by Congress: "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." *Id.* at 350. Further, Congress had already created an enforcement mechanism to handle fraudulent statements during the approval process, and state law claims would impermissibly interfere with that mechanism's preservation of the balance of interests sought by Congress. *Id.* at 348.

Here too, the federal scheme is intricate, and state law injunctions would disrupt the balance struck by the BPCIA's express consequences for noncompliance with its procedural steps. As part of that careful calibration, and "[t]o encourage parties to comply with its procedural requirements, the BPCIA includes various consequences for failing to do so." 137 S. Ct. at 1672. "Under § 262(*l*)(9)(C)," the consequence relevant here, "if an applicant fails to provide its application and manufacturing information to the sponsor—thus effectively pretermitting the entire two-phase litigation process—then the sponsor, but not the applicant, may immediately 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.'" *Id.*

The Supreme Court held that Congress's choice to impose the Section 262(*l*)(9)(C) consequence—and only that consequence—for non-provision of a biosimilar application was deliberate and should be respected. "The BPCIA's carefully crafted and detailed enforcement scheme provides strong evidence that Congress did not intend to authorize other remedies that it simply forgot to incorporate expressly." *Id.* at 1675 (quotation omitted). "The presence of § 262(*l*)(9)(C), coupled with the absence of any other textually specified remedies, indicates that Congress did not intend sponsors to have access to injunctive relief, at least as a matter of federal law, to enforce the disclosure requirement." *Id.*

Although the Court's holding was limited to the absence of a federal injunction for non-disclosure, its logic compels the conclusion that no state law injunction is available either. In *Arizona*, the Court held that Congress's choice not to "impose criminal penalties on aliens who seek or engage in unauthorized employment" meant that states could not do so—such law would be "an obstacle to the regulatory system Congress chose." 567 U.S. at 406. Here too, 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, would be frustrated if state law overrode that choice with its own injunctive (or other) relief. 137 S. Ct. at 1675 ("We assume that Congress acted intentionally when it provided an injunctive remedy for breach of the confidentiality requirements but not for breach

of § 262(*l*)(2)(A)'s disclosure requirement."). As the Chief Justice explained at oral argument, if "there's no Federal cause of action for this type of relief, then it seems odd to say . . . you get the same thing under State law." Tr. 49.

That both Section 262(*l*)(9)(C) and state law remedies would encourage compliance with the BPCIA's procedural steps does not save state law from preemption. As the Supreme Court has emphasized, "a '[c]onflict in technique can be fully as disruptive to the system Congress erected as conflict in overt policy.'" *Arizona*, 567 U.S. at 406 (quoting *Motor Coach Emps. v. Lockridge*, 403 U.S. 274, 287 (1971)). Even when state law "attempts to achieve one of the same goals as federal law," it can be preempted when it presents a "conflict in the method of enforcement." *Id.* Here the conflict in method of enforcement of the disclosure provision would be stark—injunctions to enforce compliance versus the incentive Section 262(*l*)(9)(C) provides through the prospect of immediate patent litigation. As Justice Sotomayor stated at argument, permitting a state law injunction on disclosure would "end up . . . forcing a biosimilar" applicant to engage in the patent exchange. Tr. 51. Indeed, "at every stage" of the process the sponsor "will just run to court and say, my State law remedy is force them to take the next step" (*id.* at 52), despite the BPCIA's own precise instructions on what is to happen when such a step is not taken.

The disruption to the federal scheme would be compounded by the

multiplicity of remedies different states might make available for "violations" of the BPCIA. Companies navigating this highly regulated area would face not only the BPCIA's intricate rules and the California law remedies at issue here, but also the disparate remedial schemes of all 50 states. A8 n.4 (district court observing that "Congress intended . . . a self-contained statutory scheme under the BPCIA," rather than a "hunt . . . through the laws of the fifty states"); *see Buckman*, 531 U.S. at 350 (discussing "burdens" of complying with "detailed" federal rules "in the shadow of 50 States' tort regimes"). As the Chief Justice observed, "this is a very reticulated statute with enormous consequences, and you're reading along and you finally figure it out, and all of a sudden up pops California law." Tr. 49. And "if we apply California law, then, presumably, in some circumstances, we apply the law of every other State and maybe they reach different consequences." *Id.*[4]

C. Amgen's Authorities Are Inapposite

In the Supreme Court, Amgen contended that *Rose v. Bank of Am.*, 304 P.3d 181 (Cal. 2013), and *Bates v. Dow Agroscience*, 544 U.S. 431 (2005), supported the viability of state law remedies here. Tr. 45, 49, 50. Neither does. In *Rose*, the California Supreme Court found no preemption of a UCL claim based on a

[4] During the Supreme Court argument, counsel for the United States stated: "I think there are strong arguments that this would be preempted. This is a highly detailed scheme. And if States were to start to interject different means of enforcing it on a State-by-State basis, that might wreak some havoc, but we've not taken a position on that." Tr. 27. Justice Gorsuch responded: "Exactly." *Id.*

violation of the federal Truth in Savings Act (TISA). *Rose*, 304 P.3d at 187. But it did so only because Congress had expressly "made it plain that state laws consistent with the federal statute are not superseded." *Id.* at 183. The key to the analysis was TISA's savings provision, which "preserve[d] the authority of states to regulate bank disclosures so long as state law is consistent with TISA." *Id.* at 183-84. The BPCIA has no such provision, nor is there any evidence of congressional contemplation of state law enforcement.

Bates likewise turned on an express provision in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) "address[ing] the States' continuing role in pesticide regulation." 544 U.S. at 439. The Court also pointed to the "long history" of state tort litigation in that context and stated if Congress had intended to displace it, "it surely would have expressed that intent more clearly." *Id.* at 449. No such long history exists of state regulation of biosimilar applications to FDA or patent litigation; to the contrary, those subjects are exclusively within the purview of federal law and federal courts. Nor does the BPCIA have a savings provision.[5]

[5] This Court's decision in *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (2013), is also consistent with finding preemption here. There, the violation of the California Health Code involved "state regulation of health and safety," "'a field which the States have traditionally occupied.'" *Id.* at 1355-56 (quoting *Buckman*, 531 U.S. at 347). By contrast, Amgen's claim—that Sandoz did not comply with the first step in the BPCIA information exchange—is like the preempted claim in *Buckman*. It exists "'solely by virtue of the [BPCIA] disclosure requirements.'" *Id.* at 1356 (quoting *Buckman*, 531 U.S. at 352-53).

III. THE STATE LAW CLAIMS FAIL UNDER CALIFORNIA LAW

A. Amgen's UCL Claim Fails As A Matter of California Law

The UCL itself "does not proscribe specific practices." *Cal-Tech Comm'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 973 P.2d 527, 539 (Cal. 1999). Instead, a "'business act or practice' is 'unlawful' under the unfair competition law if it violates a rule contained in *some other state or federal statute*." 137 S. Ct. at 1673 (quoting *Rose*, 304 P.3d at 185) (emphasis added). To state a claim under the "unlawful" prong, the other statute relied upon must make the challenged conduct affirmatively *unlawful*; agnosticism on lawfulness or unlawfulness is not enough. *Cal-Tech*, 973 P.2d at 539 (conduct must be "forbidden by law"). Thus, a "violation of another law is a predicate for stating a cause of action under the UCL's unlawful prong." *Graham v. Bank of Am., N.A.*, 226 Cal. App. 4th 594, 610 (2014) (citation omitted). Where there is no violation of the predicate statute, the UCL unlawfulness claim must fail. *Bothwell v. Abbott Laboratories, Inc.* (*In re Vaccine Cases*), 134 Cal. App. 4th 438, 459 (2005).

Here, Amgen has asserted a UCL "unlawful" claim based on a purported violation of the BPCIA. A73-A75. But the BPCIA does not make non-disclosure of a biosimilar application unlawful. The Supreme Court held that "[t]he BPCIA, standing alone, does not require a court to decide whether § 262(*l*)(2)(A) is mandatory or conditional." 137 S. Ct. at 1676. The Court explained that "the

mandatory or conditional nature of the BPCIA's requirements matters only for purposes of California's unfair competition law, which penalizes 'unlawful' conduct." *Id.* In other words, federal law does not render Sandoz's conduct unlawful (or lawful)—it merely specifies a federal consequence. But that conclusion also necessarily answers the California law question: unless Sandoz's conduct was unlawful as a matter of federal law—a conclusion that the Supreme Court's decision precludes—Sandoz's conduct cannot be the basis of a UCL claim.

This result is not altered by the Supreme Court statement that "[w]hether Sandoz's conduct was 'unlawful' under the unfair competition law is a state-law question" and that this Court had "erred in attempting to answer that question by referring to the BPCIA alone." *Id.* The question whether Sandoz's conduct was unlawful for purposes of the UCL is indeed a state law question, but state law in turn looks to federal law for its answer. And here, as the Supreme Court held, federal law does not make Sandoz's conduct unlawful.

Nor does the Supreme Court's description of Section 262(*l*)(2)(A) as a "disclosure requirement" (137 S. Ct. at 1668) change this conclusion. When addressing the controlling issue, the Supreme Court squarely held that the BPCIA itself does not categorize Section 262(*l*)(2)(A) as "mandatory." *Id.* at 1676.

B. Amgen Abandoned Its Conversion Claim, Which Fails In Any Event

Amgen has abandoned its separate conversion claim. Amgen's conditional

cross-petition for certiorari did not seek review of the portion of this Court's judgment affirming dismissal of that claim (794 F.3d at 1361) nor did Amgen address it in its Supreme Court merits briefing. Not surprisingly, the Supreme Court did not mention the conversion claim in its opinion, much less reverse this Court's judgment affirming its dismissal. This Court's supplemental briefing Order likewise did not address the claim. ECF177. It is no longer part of this case.

In any event, the conversion claim fails for multiple reasons. *See* ECF68 at 57-58. As this Court correctly concluded, (1) Amgen failed to establish that Sandoz's withholding of its application was a "wrongful act" and (2) given the BPCIA's authorization of an applicant's use of "'publicly-available information' regarding the reference product in its application" and the expiration of Amgen's twelve-year exclusivity period, Amgen "fail[ed] to show that it has an exclusive right to possession of its approved license on Neupogen to sustain its claim of conversion under California law." 794 F.3d at 1361. The first ground is correct for the same reason the UCL claim fails—the absence of a "wrongful act" by Sandoz; the second ground remains untouched by the Supreme Court's decision.

CONCLUSION

This case should be remanded directly to the district court. However, if the Court decides the remaining issues now, it should affirm the judgment of dismissal of Amgen's state law claims.

Dated: August 28, 2017

Respectfully submitted,

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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 August 28, 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.

Dated: August 28, 2017 /s/ Deanne E. Maynard

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