Appeal No. 2015-1499

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC., AMGEN MANUFACTURING LTD.,

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

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SUPPLEMENTAL BRIEF FOR PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING LIMITED

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AMENDED CERTIFICATE OF INTEREST

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

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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:

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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

   AMGEN INC.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this Court are:

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Pursuant to the Court's orders of July 26, 2017, July 28, 2017, and August 21, 2017 (Dkt. Nos. 177, 180, 183), Amgen submits this supplemental brief regarding the appropriate action to be taken by the Court following the Supreme Court's decision in *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017), addressing whether: (1) the BPCIA preempts state-law remedies for an applicant's failure to comply with 42 U.S.C. § 262(*l*)(2)(A); (2) Sandoz has waived any preemption defense; and (3) California law would treat noncompliance with 42 U.S.C. § 262(*l*)(2)(A) as "unlawful" under Cal. Bus. & Prof. Code § 17200. (Dkt. No. 177.)

This appeal is from the California district court's denial of Amgen's motion for a preliminary injunction; dismissal with prejudice of Amgen's state-law claims for unfair competition under Cal. Bus. & Prof. Code § 17200 (the "UCL") and conversion; and entry of judgment on Sandoz's first through fifth counterclaims. (Dkt. No. 1-2 at 3); *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1350–51 (Fed. Cir. 2015). The Supreme Court's questions on remand implicate the dismissal of Amgen's state-law claims and the entry of judgment on Sandoz's fourth and fifth counterclaims, and possibly first and second counterclaims to the extent that those counts attempt to foreclose Amgen's state-law claims.

The district court dismissed Amgen's state-law claims and entered judgment on Sandoz's counterclaims based on its holding that "[b]ecause Sandoz's actions

did not violate the BPCIA, it has committed no unlawful or wrongful predicate act to sustain Amgen's claims under the UCL and for conversion." A0014.

This Court affirmed the dismissal of Amgen's claim under the UCL because "Sandoz did not violate the BPCIA by not disclosing its aBLA and the manufacturing information according to § 262(*l*)(2)(A)." *Amgen*, 794 F.3d at 1360. Similarly, this Court affirmed the dismissal of Amgen's claim for conversion because Amgen failed to show a "wrongful act" and an "exclusive right to possession of its approved license on Neupogen." *Amgen*, 794 F.3d at 1361 (emphasis omitted). Both of these conclusions rested on the finding that Sandoz did not violate the BPCIA.

The Supreme Court found, however, that an applicant "must provide its application materials and manufacturing information," and that Sandoz's refusal to provide its aBLA and manufacturing information was a "violation of § 262(*l*)(2)(A)." *Sandoz*, 137 S. Ct. at 1669, 1675 n.2 (emphases added). By its deliberate noncompliance with the BPCIA, Sandoz committed an "unlawful" act and "wrongful" act using Amgen's license to Neupogen, sufficient, under California state law, to vacate the district court's dismissal of Amgen's UCL and conversion claims.

The district court's dismissal of Amgen's state-law claims and its entry of judgment in favor of Sandoz for its first, second, fourth, and fifth counterclaims

should be reversed, and the case remanded to the district court for further proceedings. Amgen also submits that Sandoz waived any preemption defense, and that, in any case, the BPCIA does not preempt state-law remedies for an applicant's failure to comply with 42 U.S.C. § 262(*l*)(2)(A).

I. Noncompliance with 42 U.S.C. § 262(*l*)(2)(A) is Unlawful Under Cal. Bus. & Prof. Code § 17200 and an Act of Conversion

The Supreme Court's decision left open whether California law would treat noncompliance with 42 U.S.C. § 262(*l*)(2)(A) as "unlawful" under Cal. Bus. & Prof. Code § 17200. *See id.* at 1676. First, the Supreme Court noted that this Court's prior holding—finding that no state-law claims were available to Amgen—rested on an incorrect interpretation of federal law. *Id.* In describing alternative reasons why this Court had rejected Amgen's state-law claims, the Supreme Court noted this Court's holding that Sandoz's failure "to disclose its application and manufacturing information was not 'unlawful'" because Sandoz took "a path 'expressly contemplated by' § 262(*l*)(9)(C) and § 271(e)(2)(C)(ii) and thus does not violate the BPCIA." *Id.* The Supreme Court apparently disagreed with this analysis because it held that the requirement of § 262(*l*)(2)(A) is mandatory for applicants that seek FDA approval of a biosimilar: "Under § 262(*l*), an applicant that seeks FDA approval of a biosimilar must provide its application materials and manufacturing information to the manufacturer of the corresponding biologic within 20 days of the date the FDA notifies the applicant that it has accepted the

application for review." *Id.* at 1669 (emphasis added). Nevertheless, the Supreme Court "decline[d] to resolve" the parties' dispute regarding whether § 262(*l*)(2)(A) is mandatory in all circumstances, noting that "[w]hether Sandoz's conduct was 'unlawful' under the unfair competition law is a state-law question" that cannot be decided "by referring to the BPCIA alone." *Id.* at 1676.

California law would treat an Applicant's failure to comply with 42 U.S.C. § 262(*l*)(2)(A) as "unlawful" under the UCL, Section 17200 of which reaches "any unlawful, unfair or fraudulent business act or practice." Cal. Bus. & Prof. Code § 17200. The California Supreme Court has explained that the "unlawful" prong of section 17200 "'borrows' violations of other laws and treats these violations, when committed pursuant to business activity, as unlawful practices independently actionable under section 17200 et seq." *Farmers Ins. Exch. v. Superior Court*, 2 Cal. 4th 377, 383 (Cal. 1992). "Virtually any law-federal, state, or local-can serve as a predicate for a section 17200 action." *State Farm Fire & Casualty Co. v. Superior Court*, 45 Cal. App. 4th 1093, 1102–03 (Cal. Ct. App. 1996), *abrogated on other grounds*, *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163 (Cal. 1999); *see Cel-Tech Commc'ns*, 20 Cal. 4th at 180 ("[T]he unfair competition law's scope is broad. . . . Its coverage is sweeping, embracing anything that can properly be called a business practice and that at the same time is forbidden by law." (citation and internal quotation marks omitted)). California

courts have found violations of federal statutes to meet the "unlawful" prong of Cal. Bus. & Prof. Code § 17200 claims. *See, e.g.*, *Ballard v. Equifax Check Serv., Inc.*, 158 F. Supp. 2d 1163, 1176 (E.D. Cal. 2001) (§ 17200 liability predicated on violation of federal Fair Debt Collection Practices Act); *Citizens for a Better Env't-Cal. v. Union Oil of Cal.*, 996 F. Supp. 934, 938 (N.D. Cal. 1997) (Clean Water Act); *Southwest Marine, Inc. v. Triple A Mach. Shop, Inc.*, 720 F. Supp. 805, 808 (N.D. Cal. 1989) (federal environmental laws). For example, "[v]iolations of federal statutes, including those governing the financial industry, may serve as the predicate for a UCL cause of action." *Rose v. Bank of Am., N.A.*, 304 P.3d 181, 183 (Cal. 2013) (alleging violation of the federal Truth in Savings Act).

In *Rose* and other cases, the California Supreme Court instructs that "the UCL . . . is meant to provide remedies *cumulative* to those established by other laws . . . We have long recognized that the existence of a separate statutory enforcement scheme does not preclude a parallel action under the UCL." *Id.* at 186–87 (permitting UCL claim for violation of Truth in Savings Act even though Act provided remedies for violation, because "the relief available under the UCL is quite different from the remedies formerly provided in TISA, which included actual damages, limited additional amounts, costs, and attorney fees"); *see also People v. McKale*, 602 P.2d 731, 734–35 (Cal. 1979) (permitting parallel UCL action for violations of the Mobile Home Parks Act even though Act provided a

specific statutory enforcement scheme in which the California Department of Housing or certain city or county authorities may enforce violations of the Act); *Ballard*, 158 F. Supp. 2d at 1176–77 (awarding restitution to plaintiffs for violations of the UCL based on violations of federal Fair Debt Collection Practices Act, and awarding actual damages for violations of Act); *Citizens for a Better Env't*, 996 F. Supp. at 938–39 (permitting UCL action for violations of the federal Clean Water Act even though Act provides remedies); *Southwest Marine*, 720 F. Supp. at 810 (permitting UCL action for violations of federal environmental laws and RICO even though treble damages available under RICO to compensate complainant and remedies available under environmental laws).

Consistent with California precedent interpreting California state law, Sandoz's conduct is "unlawful" under the UCL here. The relief that Amgen seeks under its parallel state-court claim under the UCL is cumulative to the BPCIA and also "quite different" from the BPCIA's remedy of a declaratory judgment action. Specifically, under the UCL, Amgen seeks remedies including restitution to compensate it for Sandoz's violation of the BPCIA that was "unlawful" under the UCL.

And here, the United States Supreme Court has already decided that the acts in which Sandoz engaged constitute a violation of the BPCIA, a federal statute: "Under § 262(*l*), an applicant that seeks FDA approval of a biosimilar must

provide its application materials and manufacturing information to the manufacturer of the corresponding biologic within 20 days of the date the FDA notifies the applicant that it has accepted the application for review." *Sandoz*, 137 S. Ct. at 1669 (emphasis added). The Court referred to failing to provide the aBLA and manufacturing information as a "violation of § 262(*l*)(2)(A)." *Id.* at 1675 n.2 (emphasis added). It thus rejected the argument that Sandoz made in this Court and in the district court, namely that the BPCIA permits an Applicant to refuse to provide that information.

Sandoz's noncompliance with 42 U.S.C. § 262(*l*)(2)(A) is also a "wrongful" act that converts Amgen's license for Neupogen under California state law. By its violation of the BPCIA, Sandoz used Amgen's license for Neupogen "without [Amgen's] authorization or permission and without satisfying the mandatory provisions of 42 U.S.C. § 262(*l*)." A0077 (Compl. ¶ 91). Although the BPCIA permits an applicant to rely on the reference product sponsor's license and demonstration of safety, purity, and potency, it does so pursuant to the very provisions that the Supreme Court determined that Sandoz violated. The district court and this Court dismissed Amgen's conversion claim based on their findings that Sandoz's actions did not violate the BPCIA. Because the Supreme Court decided that Sandoz did indeed commit a violation of the BPCIA, this Court should vacate both the dismissal of Amgen's UCL and conversion claims.

II. Sandoz Waived its Preemption Defense in this Appeal

In its Statement in Support of Remand, Sandoz noted that it had included the affirmative defense of preemption in its Answer. (Dkt. No. 174 at 10.) That is true, but it does not resolve the question. The law is clear that preemption is an affirmative defense that can be waived. *See Teutscher v. Woodson*, 835 F.3d 936, 945 n.1 (9th Cir. 2016) (finding waiver of preemption defense for failure to raise in district court or on appeal); *Russian Media Grp., LLC v. Cable Am., Inc.*, 598 F.3d 302, 309 (7th Cir. 2010) ("[F]ederal preemption [is] an affirmative defense" that can be "permanently waived."); *see also Wood v. Milyard*, 566 U.S. 463, 470 (2012) ("An affirmative defense, once forfeited, is excluded from the case." (internal quotation marks, alterations, and citations omitted)).

This Court's request for supplemental briefing on preemption acknowledges the reality that preemption has not been a disputed issue in this appeal. Sandoz repeatedly waived its preemption defense, both in the district court and also in this appeal. In the district court, Sandoz opposed Amgen's motion for a preliminary injunction and cross-moved for judgment on the pleadings, affirmatively stating at oral argument: "We have not argued preemption of the state law claims." A1854. Accordingly, the district court did not consider preemption in denying Amgen's motion, dismissing Amgen's state-law claims, and entering judgment on Sandoz's counterclaims. At oral argument in this Court, Sandoz's counsel acknowledged

that Sandoz had not argued preemption in the district court. Oral Argument at 44:55–45:08, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-1499.mp3 ("JUDGE CHEN: How come you didn't argue preemption? MS. MAYNARD: Well, because the UCL is self-preempting, Judge Chen. So the UCL expressly provides that unless expressly provided elsewhere, and here the remedies are exclusive."). Sandoz has litigated this case for nearly three years, including litigating Amgen's state-law claims at every level of the federal courts, without ever pressing its affirmative defense of preemption, despite repeated questions from the courts. Sandoz should not now be permitted to reverse course and retract its waiver.

On the contrary, this appeal arises from the district court's denial of Amgen's motion, dismissal of Amgen's state-law claims, and entry of judgment on Sandoz's counterclaims, and thus Sandoz's waiver in district court carries forward to this appeal. *See, e.g.*, *HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1283 (Fed. Cir. 2012) ("Because HTC never attacked the adequacy of the algorithm in the '830 patent when given an opportunity to do so before the district court, however, HTC cannot lodge that attack for the first time here."); *L.E.A. Dynatech, Inc. v. Allina*, 49 F.3d 1527 (Fed. Cir. 1995) (refusing to hear on appeal an argument not timely raised below because, "for the court to consider the issue

would allow [the appellant] to evade district court consideration."). Like the district court, this Court did not address preemption in its underlying decision, noting that, "In its cross-motion for judgment on the pleadings, Sandoz did not argue preemption as a defense to Amgen's state-law claims, and thus the district court did not consider that issue." *Amgen*, 794 F.3d 1347, 1360 n.5 (Fed. Cir. 2015).

Thus, the Court should not address preemption now, nor should the issue be remanded to the district court. While this Court has discretion as to what issues to take up in individual cases, "[i]t is the general rule, of course, that a federal appellate court does not consider an issue not passed upon below." *See Singleton v. Wulff*, 96 S. Ct. 2868, 2877 (1976). "This rule fosters sound policies. It ensures finality in litigation by limiting the appealable issues to those a lower court had an opportunity to, and did, address. The rule also conserves judicial resources because it prevents parties from undoing a lower court's efforts—sometimes spanning years of litigation—based on an error that a lower court could have considered and corrected." *HTC*, 667 F.3d at 1281–82.

This is not an exceptional case that warrants departure from the general rule regarding waiver. Sandoz knew this appeal would consider novel statutory-interpretation issues, yet Sandoz chose not to inject preemption into the case and instead to argue on the merits of the state-law claims. It has not identified any

reason why this court might "excuse" Sandoz's "failure to preserve an issue." *HTC*, 667 F.3d at 1282; *see also L.E.A. Dynatech*, 49 F.3d at 1531–32.

III. The BPCIA Does Not Preempt State-Law Remedies for Failure to Comply with 42 U.S.C. § 262(*l*)(2)(A)

Federal law may preempt state law in three ways: express preemption; field preemption; and/or conflict preemption. *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1323 (Fed. Cir. 1998), *rev'd on other grounds*, *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999). None of those doctrines preempts Amgen's claims under California state law for unlawful conversion and for unfair competition under Cal. Bus. & Prof. Code § 17200 (the "UCL"). A0073–79 (Compl. ¶¶ 77–97).

A. There is No Express Preemption

The BPCIA does not contain an express preemption provision, or other language referring to and preempting state-law remedies. Thus, there is no express preemption here. *Hunter Douglas*, 153 F.3d at 1332.

B. There is No Conflict Preemption

The BPCIA does not conflict with Amgen's state-law claims for conversion and under the UCL. A state law conflicts with federal law when it poses "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Wyeth v. Levine*, 555 U.S. 555, 589 (2009). Here, the relevant federal law—specifically 42 U.S.C. § 262(*l*) of the BPCIA—is part of the federal

patent laws, "enabl[ing] the parties to bring infringement actions at certain points in the application process." *Sandoz*, 137 S. Ct. at 1670. A state "cannot, under some other law, such as that forbidding unfair competition, give protection of the kind that clashes with the objectives of the federal patent laws." *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 231 (1964). The Federal Circuit has held that the patent laws will not preempt state-law claims if the state-law claims include additional elements not found in the federal patent law cause of action and are not an impermissible attempt to offer patent-like protection to subject matter addressed by federal law. *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1306 (Fed. Cir. 1999).

First, both Amgen's UCL and conversion claims do not "clash" with the objectives of the BPCIA and federal patent laws. *See Sears*, 376 U.S. at 231. The Supreme Court stated that one of the objectives of the BPCIA is to "facilitate[] litigation during the period preceding FDA approval so that the parties do not have to wait until commercial marketing to resolve their patent disputes." *Sandoz*, 137 S. Ct. at 1670. That is accomplished when "the parties comply with each step outlined in the BPCIA." *Id.* at 1672. The UCL supports compliance with the BPCIA and its objectives, rather than conflicting with them. Conversion law too supports compliance with the BPCIA where an applicant converts a reference product sponsor's data by using it without satisfying the mandatory provisions of

42 U.S.C. § 262(*l*). Although the BPCIA gives permission for a biosimilar applicant to rely on a sponsor's data, this is a limited exception that does not authorize conduct outside the provisions of the BPCIA.

Second, Amgen's UCL and conversion claims include additional elements that are not addressed by the BPCIA or found in the patent litigation facilitated by the BPCIA. Amgen's UCL claim "prevents unethical and oppressive business practices," *Rodime*, 174 F.3d at 1306, and separately requires: a showing that an act is an unlawful, unfair, or fraudulent business act; a requirement to show an injury in fact; and a causation requirement, i.e., that there was "lost money or property as a result of the unfair competition." Cal. Bus. & Prof. Code §§ 17200, 17204. Amgen's claim for conversion involves property rights that are not patent rights, namely Amgen's FDA license for Neupogen, and also requires showing damages, in addition to ownership of the property and wrongful disposition. *See G.S. Rasmussen & Assocs., Inc. v. Kalitta Flying Serv., Inc.*, 958 F.2d 896, 906 (9th Cir. 1992).

Third, the injuries described and the relief sought in Amgen's Complaint for its UCL and conversion claims are different than and independent from the remedy provided by the BPCIA in § 262(*l*)(9)(C) to bring a declaratory judgment action, and, moreover, any relief Amgen would ultimately seek for its patent infringement claims. For its UCL claim, Amgen alleged that it "suffered economic injury to

[its] business in the form of lost money that was spent to monitor and respond to [Sandoz's] acts of unfair competition." A0074–75 (Compl. ¶ 82). And Amgen sought relief in the form of an injunction and full restitution for the benefits it will lose and Sandoz will obtain as a result of such unlawful business practices. A0075 (Compl. ¶¶ 83, 85); A0081 (Prayer for Relief ¶¶ B–C). As to its conversion claims, Amgen alleged that "Defendants' use of the license for NEUPOGEN® (filgrastim) to obtain a governmental privilege (FDA approval to market, manufacture, import, and sell the Sandoz biosimilar product for use in the United States) for Defendants' own benefit and profit is an act of conversion" when used "without Plaintiffs' authorization or permission and without satisfying the mandatory provisions of 42 U.S.C. § 262(*l*)." A0077 (Compl. ¶ 91). Amgen sought relief in the form of an injunction, compensatory damages, restitution, and punitive damages for Sandoz's acts of conversion. A0078–79 (Compl. ¶ 97); A0081 (Compl. Prayer for Relief ¶¶ F–H).

These injuries are entirely separate from Amgen's ability to bring a declaratory judgment pursuant to § 262(*l*)(9)(C) and indeed, are also separate from whether Amgen prevails on its patent law claims. The state-law injuries do not depend on the resolution of Amgen's patent disputes. Likewise, in *HIF Bio, Inc. v. Yung Shin Pharmaceuticals Industrial Co., Ltd.*, this Court held that patent law was not essential to plaintiffs' California state-law causes of action for conversion

and unfair competition: "For example, patent law is not essential to plaintiff's cause of action for conversion . . . Because plaintiffs could establish conversion by reference to the defendants' alleged misappropriation of 'experiments, pre-publication experimental data, and nonpublic, pre-publication drafts of papers,' an alternative, non-patent theory exists which entitles plaintiffs to relief . . . Inventorship is likewise not essential to the causes of action for fraud, unfair competition, breach of implied contract, or ownership." 600 F.3d 1347, 1355–56 (Fed. Cir. 2010); *accord Regents of the Univ. of Cal. v. Roger Jinteh Arrigo Chen*, No. 16-cv-07396-EMC, 2017 WL 3215356, at *7 (N.D. Cal. July 26, 2017) (a California state-law conversion claim was not preempted because its claims depended on "factual questions of when certain of [inventor's] actions occurred rather than a more complete determination of inventorship.").

C. There is No Field Preemption

While only the federal government can issue a patent and only federal courts can resolve patent-infringement suits, in *Hunter-Douglas* this Court held that patent law does not fully preempt related state-law doctrines—there, state unfair-competition laws. 153 F.3d at 1333 (federal patent law does not "occupy exclusively the field pertaining to state unfair competition law").

"In all pre-emption cases, and particularly in those in which 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." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal citations omitted). "Under field preemption, state law is preempted when it regulates conduct in a field that Congress intends the federal government to occupy exclusively. Such an intent may 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,' or when congressional legislation '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." *Hunter Douglas*, 153 F.3d at 1332 (internal citations omitted).

Here, the BPCIA does not preempt Amgen's 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). The federal remedy—if it is one at all—of § 262(*l*)(9)(C) to bring a declaratory judgment action does not preempt state-law claims because it does not remedy the competitive, but unlawful, advantage given to Sandoz by not complying with the BPCIA disclosure requirement. Nor does it remedy Sandoz's "wrongful act" in converting Amgen's license for Neupogen without Amgen's

authorization or permission and without satisfying the mandatory provisions of 42 U.S.C. § 262(*l*).

A state-law remedy provides sponsors with a meaningful remedy by protecting against and compensating for applicants' unlawful behavior and unauthorized use of the sponsors' property interests to their competitive disadvantage. When the applicant fails to provide its aBLA and manufacturing information, the applicant's information is secret and unavailable to the sponsor. Detection of the applicant's patent infringement may be evaded, and sponsors may be forced to bring a lawsuit as to their patents (which could potentially number in the hundreds) without knowing what information the subsection (k) applicant has disclosed to the FDA regarding the proposed biosimilar product which is the accused product in the lawsuit.[1] Even more significantly, the reference product sponsor might not even know that the applicant submitted its application to FDA in the first instance. When the applicant fails to provide its aBLA, a conversion claim or an action under the UCL provides the reference product sponsor with an opportunity to remedy anticompetitive behavior, which supplements (and does not

[1] For example, in a recent BPCIA case without a dispute over compliance with § 262(*l*)(2)(A), a reference product sponsor alleged that its innovative drug product "resulted in more than 100 issued United States patents concerning the [drug] product, 74 of which [the sponsor] has identified as infringed." *AbbVie Inc. v. Boehringer Ingelheim International GmbH*, Case No. 1:17-cv-01065, Dkt. No. 1 at ¶ 1 (D. Del. Aug. 2, 2017).

replace or occupy the same field as) the BPCIA's patent-dispute resolution process.

State-law remedies like Amgen seeks here provide the opportunity to compensate Amgen in a way that the federal "remedy" in § 262(*l*)(9)(C) cannot. For example, Amgen seeks damages for its state-law claims such as restitution for Sandoz's acts of unfair competition, and compensatory damages, restitution, and punitive damages for Sandoz's acts of conversion. *See* A0081 (Compl. Prayer for Relief ¶¶ B, F–H).

To be clear, Amgen recognizes that the Supreme Court has held that the statute does not provide any federal remedy other than § 262(*l*)(9)(C) for noncompliance, and that the statute thus contemplates a regime in which the reference product sponsor is forced to file a patent lawsuit without having any information from the subsection (k) applicant. But the statute does not foreclose the opportunity for the reference product sponsor to seek a remedy under state-law where, as here, Sandoz is reaping the benefits of Amgen's data under the abbreviated subsection (k) pathway but without having complied with the information-exchange requirements of subsection (*l*) which apply to subsection (k) applicants.

In summary, Sandoz's noncompliance with 42 U.S.C. § 262(*l*)(2)(A) was a violation of the BPCIA that was "unlawful" under California's UCL and

"wrongful" under California conversion law. This Court should so hold. Furthermore, Sandoz waived any preemption defense in this appeal, and the Court need not address preemption now, nor should the issue be remanded to the district court. In any case, the BPCIA does not preempt Amgen's state-law claims.

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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.

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