No. 2015-1499

United States Court of Appeals

for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH,

Defendants-Appellees.

Appeal from the United States District Court for the Northern District of California in Case No. 3:14-cv-4741, Judge Richard Seeborg

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CORRECTED BRIEF FOR ABBVIE INC. AS AMICUS CURIAE SUPPORTING PLAINTIFFS-APPELLANTS

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CERTIFICATE OF INTEREST

Counsel for amicus curiae AbbVie Inc. certifies the following pursuant to Fed. R. App. P. 26.1 and Fed. Cir. R. 29(a) and 47.4:

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

   AbbVie 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:

   AbbVie Inc.

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

   None.

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

   Latham & Watkins LLP: Gregory G. Garre, Michael A. Morin, David P. Frazier, Melissa Arbus Sherry, Casey L. Dwyer, Robert J. Gajarsa.

April 13, 2015

/s/ *Melissa Arbus Sherry*
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INTEREST OF AMICUS CURIAE[1]

AbbVie is an innovative biopharmaceutical company which discovers, develops, and markets drugs for the treatment of many diseases, including HIV, hepatitis C, cancer, multiple sclerosis, and Parkinson's disease. One of AbbVie's drugs, HUMIRA®, comprises the monoclonal antibody adalimumab and has been used to treat hundreds of thousands of patients suffering from diseases as diverse as rheumatoid arthritis, psoriasis, and Crohn's disease. AbbVie continues to explore new indications for HUMIRA® in an effort to improve the lives of even more patients.

HUMIRA® is one of a growing category of drugs known as biologics. Biologics are complex proteins which are manufactured in living cells rather than by chemical synthesis. Biologics can treat diseases very effectively, but because of their complexity are difficult to develop and manufacture. In addition to HUMIRA®, AbbVie is developing new biologics that may one day also be the subject of biosimilar applications under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, § 7001 *et seq.*, 124 Stat. 119, 804 (2010). AbbVie thus has a significant interest in ensuring a fair system of resolving patent disputes surrounding the approval of biosimilar products.

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[1] No counsel for any party authored this brief in whole or in part. No party or a party's counsel made a monetary contribution to this brief's preparation or submission. All parties have consented to the filing of this brief.

The district court's interpretation of the BPCIA cannot be squared with the law's text and upends the statutory scheme Congress enacted to resolve such disputes. Accordingly, AbbVie has a substantial interest in the proper resolution of this appeal.

INTRODUCTION

Just as with the enactment of the Hatch-Waxman Act some thirty years ago, the courts—and especially *this* Court—are about to enter a new era of patent litigation. As it did in 1984 with small molecule drugs, Congress has now created an abbreviated approval process for biosimilar versions of biologic products, which allows biosimilar companies to utilize the data and work of innovator companies and sets forth a specific set of procedures when a biosimilar company has chosen to follow that path. And just as Hatch-Waxman patent litigation has become ubiquitous over the past three decades, the same is likely to happen with biosimilars litigation.

The outcome of this appeal will have a profound effect on the transparency, efficiency, and fairness of the legal process going forward. If Amgen's positions are adopted—and Congress's directives are enforced—parties will enter the litigation process well informed; they will be able to identify the patents truly at issue, engage in good-faith negotiations, narrow their disputes, and litigate only those issues that warrant the courts' time and attention. If Sandoz were to prevail,

the entire biosimilar litigation process would become a free-for-all, where biosimilar companies would utilize the data and work of innovator companies but refuse to provide basic information about their products, including their compositions, indications, formulations, and manufacturing processes, as well as the timing of their planned launches, leaving innovators to blindly guess as to which patents they should sue on and when. The first option will lead to more focused cases, more transparency, and more frequent and earlier settlements; the second will burden the courts with inefficient and protracted litigation for years to come.

Given these stakes, this brief addresses two questions, both of which present issues of first impression. *First*, does subsection (*l*) of the BPCIA set forth mandatory notice-and-exchange procedures that subsection (k) applicants and reference product sponsors are required to follow (as Amgen argues), or does it merely set forth optional suggestions that subsection (k) applicants are free to disregard (as Sandoz argues and as the district court held)? *Second*, does federal law expressly or implicitly preempt Amgen's state-law claims?

By ruling for Sandoz on these issues, the district court eviscerated the BPCIA, transforming it from a carefully crafted statute designed to balance competing interests and narrow and streamline patent litigation into an entirely optional procedure that biosimilar companies are ignoring. The district court's

rulings cannot be squared with the statutory text, structure, history, or purpose of the BPCIA, find no support in the governing case law, and upend a critically important statutory scheme. This Court should correct those fundamental errors by reversing the district court's decision.

ARGUMENT

I. THE NOTICE-AND-EXCHANGE PROCESS IN SECTION 262(*l*) OF THE BPCIA IS MANDATORY

The district court held that, after submitting an application for a biologic follow-on product with the Federal Food and Drug Administration ("FDA"), a subsection (k) applicant has two options: (1) "comply" with the BPCIA's sequential notice-and-exchange provisions, or (2) "elect" not to comply. In the district court's view, either option is entirely "permissible" and a decision "not to comply" does not violate any law. A9-10, A18-19. This interpretation contravenes the plain text of the statute, ignores its legislative history, and undermines congressional intent. Applying settled canons of construction, the statutory provisions are capable of only one interpretation: the notice-and-exchange provisions are mandatory and a subsection (k) applicant's failure to comply with the statute is unlawful.

A. The Plain Text Of The BPCIA Establishes That The Notice-And-Exchange Process Is Mandatory

1. "Shall" Connotes A Mandatory Directive, Particularly When Juxtaposed With The Permissive "May"

Congress's choice of words is unmistakable and dispositive. It repeatedly used the term "shall" to describe the notice-and-exchange obligations in § 262(*l*). *See, e.g.*, 42 U.S.C. § 262(*l*)(2)(A) (applicants "shall provide" copies of application to reference product sponsor); *id.* § 262(*l*)(3)(B)(ii) (applicants "shall provide" sponsor "a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion . . . that such patent is invalid"). Congress characterized the notice-and-exchange activities as "'required,'" and referred to non-performance as a "'fail[ure]'" to follow the law. Amgen Br. 38 (citations omitted). And when a particular activity was optional, it chose a different verb: "may." *See, e.g.*, 42 U.S.C. § 262(*l*)(2)(B) (applicant "may provide" sponsor "additional information requested by or on behalf of the reference product sponsor"); *id.* § 262(*l*)(3)(B)(i) (applicant "may provide" sponsor "a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted").

"Statutory instructions using the term 'shall' are ordinarily treated as mandatory." *Gilda Indus., Inc. v. United States*, 446 F.3d 1271, 1282 (Fed. Cir. 2006); *see Alabama v. Bozeman*, 533 U.S. 146, 153 (2001) ("'The word "shall" is

ordinarily 'the language of command.'" (citations omitted)); *United States v. Monsanto*, 491 U.S. 600, 606-07 (1989) ("Congress could not have [a] chosen stronger word[than "shall"] to express its intent that forfeiture be mandatory."); *Air Line Pilots Ass'n, Int'l v. US Airways Grp., Inc.*, 609 F.3d 338, 341-42 (4th Cir. 2010) ("Congress's use of the obligatory 'shall'" makes clear that private persons are "required" to perform the specified act.); *see also* Amgen Br. 37 (citing cases).

Indeed, in *National Federation of Independent Business v. Sebelius*, 132 S. Ct. 2566 (2012) ("*NFIB*"), the Supreme Court examined the meaning of the term "shall" in another section of the Affordable Care Act (of which the BPCIA is a part) and concluded that it was most "natural[ly]" read as imposing a "command[]" on persons to buy health insurance. *Id.* at 2593 ("The most straightforward reading of the mandate is that it commands individuals to purchase insurance. After all, it states that individuals '*shall*' maintain health insurance.") (opinion of Roberts, C.J., for a majority of the Court) (emphasis added)[2]; *id.* at 2652 (Scalia, J., dissenting) (rejecting argument that the "mandate" "shall" can be read "to mean 'may,'" and reasoning that the failure to purchase health insurance is

[2] The Chief Justice adopted a construction contrary to that "straightforward" reading *only* because the provision "would otherwise violate the Constitution." *NFIB*, 132 S. Ct. at 2594. The constitutional avoidance canon does not apply here and cannot save the district court's departure from the plain meaning of "shall."

"unquestionably" a "violation of the law" where the "minimum-coverage" provision is in a section entitled "Requirements," where it "commands" that individuals "shall" obtain coverage, and where its speaks of an individual "fail[ing]" to meet the "requirement" imposed).

The juxtaposition of "shall" and "may" reinforces the ordinary meaning of "shall." "[W]hen the same [provision] uses both 'may' and 'shall,' the normal inference is that each is used in its usual sense—the one act being permissive, the other mandatory." *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947); *see United States ex rel. Siegel v. Thoman*, 156 U.S. 353, 359-60 (1895) (When Congress uses the "special contradistinction" of "shall" and "may," no "liberty can be taken with the plain words of the statute"; Congress is "indicating command in the one and permission in the other."); *Air Line Pilots Ass'n*, 609 F.3d at 342 ("[T]hat the word 'may' is to be given a meaning distinct from the word 'shall' is further bolstered by Congress's use of both words in close proximity to one another, signaling that the contrast was not accidental or careless."); *Beaty v. FDA*, 853 F. Supp. 2d 30, 37-38 (D.D.C. 2012) ("[I]t is clear that Congress intended for the word 'shall' to have a different meaning than 'may'—specifically, to be mandatory rather than permissive."), *aff'd in part, vacated in part sub nom. Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013); *see also* Amgen Br. 37-38.

Accordingly, the statute could hardly be more clear: a subsection (k) applicant "shall" (*i.e.*, "must") do certain things, it "may" (or "may not") do other things, and if it fails to do any of the mandatory acts, it has violated the BPCIA (*i.e.*, it has acted "unlawfully").

2. The Broader Statutory Context Further Confirms That The Notice-And-Exchange Process Is Mandatory

"[A] fundamental canon of statutory construction [is] that the words of a statute must be read . . . with a view to their place in the overall statutory scheme." *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989). Here, the "overall statutory scheme" reinforces what the plain text makes clear: the notice-and-exchange provisions are mandatory.

Congress used "shall" throughout § 262 to indicate a mandatory command to act. No one—not even Sandoz—could contend that Congress's use of "shall" outside of subsection (*l*) describes merely optional conduct. For example, Congress stated that "[n]o person *shall* introduce or deliver for introduction into interstate commerce any biological product unless . . . a biologics license . . . is in effect for the biological product." 42 U.S.C. § 262(a)(1)(A) (emphasis added). It instructed that an application "*shall* include information demonstrating that" the product "is biosimilar to a reference product," and that no persons "*shall* falsely label or mark any package." *Id.* § 262(k)(2)(A)(i), (b) (emphases added). It would be untenable to argue that Congress meant for such directives to be permissive,

i.e., that individuals can decide for themselves whether to sell a "biological product" without a "biologics license," or whether to falsely mark a biologic product.

Yet the district court held that Congress's use of "shall" in subsection (*l*) means something fundamentally different than what it means everywhere else in § 262. That defies a basic tenet of statutory construction: "identical words and phrases within the same statute should normally be given the same meaning." *Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007); *see United States v. Tinklenberg*, 131 S. Ct. 2007, 2019 (2011) ("Identical words used in different parts of a statute are presumed to have the same meaning . . . ."); *Frankl v. HTH Corp.*, 650 F.3d 1334, 1353 (9th Cir. 2011) (similar). If § 262's licensing, application, and labeling requirements are all mandatory, there is no justification for reading the same "shall" directives in subsection (*l*) any differently.

Even within subsection (*l*), contextual clues counsel strongly against the district court's "optional" reading. If the notice and information required by subsection (*l*)(2)(A) is something that the subsection (k) applicant can elect to provide (or not), then so are all the other notice-and-exchange requirements—including the requirement that the applicant provide the reference product sponsor with at least 180-days' notice before commercial marketing. In this case, the

parties have primarily disputed *when* that commercial-marketing notice is required.[3] But, as Amgen notes (Br. 45), to the extent the district court also appeared to hold that *no* notice of commercial marketing is required at all, it further demonstrates why the district court is wrong.

The 180-day notice provision is meaningless if the applicant is not required to provide any notice. *See TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (statutes must be construed so that "'no clause, sentence, or word shall be superfluous, void, or insignificant'" (citation omitted)). Without the commercial notice requirement, an applicant could receive approval of a biosimilar and then immediately launch at risk without any warning to innovators. In that event, the innovator will not have time to even file for a temporary restraining order before the biosimilar's launch, let alone seek a preliminary injunction, take any necessary discovery, or obtain a ruling *before* the status quo is disturbed. Leaving aside potential irreparable harm, the consequence would be uncertainty in the markets and the marketplace and confusion among patients and doctors alike. Sandoz's argument, if taken to its logical conclusion, makes a mockery of the carefully worded statute. Here and elsewhere, "shall" means "shall."

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[3] AbbVie agrees with Amgen that the requisite notice of commercial marketing can only be provided after FDA licensure as a matter of statutory text and of common sense. *See* Amgen Br. 45-52; *Sandoz, Inc. v. Amgen, Inc.*, No. 13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12, 2013), *aff'd on other grounds*, 773 F.3d 1274 (Fed. Cir. 2014).

3. Subsection (*l*)(9) Does Not Make The Notice-And-Exchange Provisions Optional

Despite overwhelming evidence that Congress used "shall" in its ordinary way, the district court nevertheless concluded that subsection (*l*)(9) transforms the extensive notice-and-exchange process into advisory guidelines. In the district court's view, a subsection (k) applicant can "elect" between two options: (1) follow the procedures outlined in subsection (*l*)(2)-(8), or (2) take the risk that the reference product sponsor will bring a declaratory judgment action. Contrary to the district court's conclusion, that reading of the statute is neither "fair" (A9) nor defensible.

According to the district court, subsection (k) applicants will be "encourage[d]" to comply with the notice-and-exchange provisions in order to avail themselves of the "carrot" of the "safe harbor" set forth in (*l*)(9)(A), *i.e.*, in order to avoid a declaratory judgment action on potentially infringed patents. A10. But the reality is that premature and uninformed patent infringement litigation is precisely what subsection (k) applicants want. To the best of amicus' knowledge, not a single applicant to date has complied with the notice-and-exchange process set forth in the BPCIA. Rather, applicants have made clear that they *prefer* immediate court actions, presumably so that they can deny the innovator the prelitigation discovery set forth in the statute. Accordingly, as a practical matter, subsections (*l*)(9)(B) and (C) impose no real "consequence" for noncompliance

and no incentive to comply. By making compliance optional for the subsection (k) applicant, the district court has effectively rendered the notice-and-exchange provisions a nullity.

Even if subsection (*l*)(9) could be viewed as a true "consequence" or "remedy" for noncompliance, that would not render the notice-and-exchange provisions optional. Pairing a directive ("you shall do X") with a penalty or "remedy" for failing to comply ("if you don't do X, then Y"), does not indicate a discretionary choice. So too here: when Congress said that a subsection (k) applicant "shall" provide the reference product sponsor with the BLA and other manufacturing information, and that if it "fails" to do so, the reference product sponsor may bring a declaratory judgment action, it was not transforming that "failure" into a lawful act.

That common sense reading is reinforced by the detailed notice-and-exchange provisions. Congress enacted a carefully reticulated patent disclosure scheme, complete with detailed confidentiality provisions applying to the "exchange of information" (42 U.S.C. § 262(*l*)(1)(A)-(H)), specified time limits for different disclosures (*e.g.*, *id.* § 262(*l*)(2)(A) (20 days for copy of BLA and manufacturing information); *id.* § 262(*l*)(3) (60 days for provision of patent list, response to patent list, and response to the response)), provisions for good-faith negotiations and deciding which patents to litigate (*id.* § 262(*l*)(4)-(6)), means of

addressing later-issued patents (*id.* § 262(*l*)(7)), and commercial-marketing notice requirements that trigger more procedures still (*id.* § 262(*l*)(8)). It is impossible to read subsection (*l*) from beginning to end and conclude that Congress went through all of that effort, provided all of those details, and considered all of the potential alternatives, only to conclude by saying in (*l*)(9): "but do whatever you want." *See TRW Inc.*, 534 U.S. at 31 (statutes must be construed so as to avoid rendering portions of the statute "'insignificant'" (citation omitted)). And if Congress really wanted to provide subsection (k) applicants a choice between options, it would not have done so in such an opaque manner. *See Pilgrim's Pride Corp. v. Comm'r*, 779 F.3d 311, 316-17 (5th Cir. 2015) (refusing to "ascribe to Congress 'an extravagant preference for the opaque'" or to assume that Congress chose to legislate "'in an unusually backhanded manner'" (citations omitted)); *cf. Whitman v. Am. Trucking Associations*, 531 U.S. 457, 468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.").

B. The Legislative History Of The BPCIA Confirms That The Notice-And-Exchange Process Is Mandatory

The legislative history of the BPCIA confirms that Congress envisioned a mandatory process of notice and information exchange in § 262(*l*). That is evident from the change in statutory language from "may" to "shall" in different iterations of the BPCIA, and a House Report describing the provisions as "mandatory." In

contrast, nothing in the legislative history suggests that Congress intended to permit subsection (k) applicants to treat the mandated notice-and-exchange provisions as optional.

1. The Exchange Requirements In The BPCIA Were Changed From Optional To Mandatory During Drafting

Section 262(*l*) evolved during the legislative process from a discretionary system of information exchanges into the current mandatory regime. Congress "considered a number of schemes for communication between the parties regarding patents relevant to biosimilar market entry"; "[t]hese included a procedure in which the reference product sponsor and the applicant had the option to notify each other regarding patents they deemed relevant and a mandatory information exchange process." Krista Hessler Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 671, 757 (2010) (footnote omitted). "[U]ltimately," Congress "selected the latter option." *Id.*

For example, an early Senate draft allowed a biosimiliar applicant to choose whether to disclose its application to the reference sponsor. *See* S. 623, 110th Cong. § (3)(a)(2)(k)(17)(E) (2007) ("An applicant or prospective applicant for a comparable biological product under this subsection may not be compelled, by court order or otherwise, to initiate the procedures set forth in this paragraph. Nothing in this paragraph requires an applicant or a prospective applicant to invoke

the procedures set forth in this paragraph."). Notably, this earlier version used the verb "may" rather than "shall." *See, e.g.*, *id.* § (3)(a)(2)(k)(17)(B) ("At any time after submitting an application under this subsection, the applicant *may* provide a notice of the application with respect to any one or more patents . . . ." (emphasis added)).

In a later version of the bill, however, the permissive language was removed and the exchange provisions became mandatory: "Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant . . . *shall* provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k) . . . ." S. 1695, 110th Cong. § 2(a)(2)(*l*)(2)(A) (2007) (emphasis added). This last version—with the mandatory command "shall"—became the BPCIA. The change in the operative language from permissive to mandatory is compelling evidence that Congress consciously rejected the district court's "optional" approach. *See Chickasaw Nation v. United States*, 534 U.S. 84, 93 (2001) ("We ordinarily will not assume that Congress intended 'to enact statutory language that it has earlier discarded in favor of other language.'" (citations omitted)); *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987) ("Few principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded

in favor of other language." (citations omitted)); *Figueroa v. Sec'y of Health & Human Servs.*, 715 F.3d 1314, 1324 (Fed. Cir. 2013) (finding change in draft language for Vaccine Act indicative of Congress's intent); *In re Town & Country Home Nursing Servs., Inc.*, 963 F.2d 1146, 1151 (9th Cir. 1991) (when "the final version of a statute deletes language contained in an earlier draft, a court may presume that the earlier draft is inconsistent with ultimate congressional intentions").

2. The Congressional Report Discussing The BPCIA Described The Exchange Provisions As Mandatory

For the enacted version of the BPCIA, the House Report describes the exchange provisions as mandatory. Specifically, the report explains that "[t]he provision would set forth a process governing patent infringement claims against an applicant or prospective applicant for a biological product license," and that "[i]t would also establish new processes for identifying patents that might be disputed between the reference product company and the company submitting a biosimilar application as well as *a multistep patent resolution process*." *See* H.R. Rep. No. 111-299, pt. 1, at 742 (2009) (emphasis added). It continues: that "provision stipulates that all biological product applications *would have to be submitted under the requirements* of PHSA section 351 [now codified as BPCIA § 262]." *Id.* (emphasis added).

A report by Congress's research service unit, published months later, provides the same account. Wendy H. Schacht & John R. Thomas, Cong. Research Serv., R 41270, *P.L. 111-148: Intellectual Property Provisions for Follow-On Biologics* 5 (2010) ("The legislation *requires* that within 20 days after the Secretary of Health and Human Services publishes a notice that its application has been accepted for review, the biosimilar or interchangeable product applicant *will provide* the reference product sponsor with details concerning the product and its production.") (emphases added); *see also id.* (describing each "shall" step in the sequential notice-and-exchange process as something the parties "are required" to do and describing each "may" step as something the parties are "allowed" to do).

C. Treating The Notice-And-Exchange Provisions As Mandatory Furthers The Statutory Purposes Of The BPCIA, Whereas An "Optional" Reading Undermines Them

1. As With The Hatch-Waxman Act, Congress Aimed To Provide A Mandatory System For Ascertaining Patent Rights

Congress was well aware that the new, abbreviated FDA process it created for follow-on biologics would give rise to patent disputes. It had already been down this road with small molecule drugs in the Hatch-Waxman Act. Although Congress recognized that biologic products presented different challenges, and thus required different procedures, the desired end was the same: a *mandatory* process through which the innovator and biosimilar would identify patent disputes

and narrow or resolve them (to the extent possible) *before* launch. *See generally Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1276 (Fed. Cir. 2014) (Congress "borrow[ed] from" the Hatch-Waxman Act in crafting the BPCIA).

While the BPCIA's notice and exchange provisions operate differently from the certification procedures in Hatch-Waxman, they require similar things—notice of an application, information exchange, and the opportunity for the branded drug company to seek an injunction to prevent a generic or biosimilar from launching in the face of relevant patents. Instead of an "*Orange Book*" repository of patent information for biologic drugs, Congress created the BPCIA's private notice-and-exchange process. *See* Michael P. Dougherty, *The New Follow-On-Biologics Law: A Section by Section Analysis of the Patent Litigation Provisions in the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L.J. 231, 234 (2010). But it fully expected its replacement scheme to achieve the same objective: the orderly litigation of patent rights to facilitate efficient dispute resolution with as much information as possible. *See Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary* ("*July 2009 Housing Hearing*"), 111th Cong. 9 (2009) (statement of Rep. Anna Eshoo) (the proposed notice and exchange provisions "will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the

biosimilar product"); *id.* at 196 (statement of Teresa Stanek Rea, President, American Intellectual Property Law Association) ("The pending bills in the House attempt to develop procedures parallel to the Hatch-Waxman Act. They include mechanisms for prelaunch patent dispute resolution . . . ."); Letter from C. Landis Plummer, Acting Sec'y, FTC, to Rep. Frank Pallone 6-9 (May 2, 2008) (advising that biologics legislation includes a "pre-marketing patent litigation process" that "involve[d] private exchange of patent information").

Adopting the district court's (and Sandoz's) construction of the BPCIA's notice-and-exchange provisions undermines Congress's intent for informed and streamlined litigation of patent issues related to biosimilars.

2. The BPCIA Seeks To Ensure That Innovators Can Enforce Their Patent Rights From A Position Of Knowledge

As the district court recognized (but did not effectuate), Congress's overarching objective in the BPCIA was to balance the need for patient access to biosimilars with the need to protect innovators' intellectual property rights. *See* A3; Amgen Br. 4, 21-22; BPCIA of 2009, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010) (purpose of law is to establish a "biosimilars pathway balancing innovation and consumer interests"). One of the ways Congress sought to achieve this balance was by laying out a detailed notice-and-exchange process, so that innovators would be guaranteed sufficient time and opportunity to evaluate and assert their patent rights before a biosimilar launch. *See* Amgen Br. 38-41.

According to Sandoz, subsection (*l*)'s information exchanges are unnecessary because sponsors can simply obtain all relevant information during discovery, after a patent suit has commenced. But this ignores the statute Congress enacted. Congress intentionally shifted the information disclosures that would otherwise occur as part of the discovery process to a period in time before litigation commences, so that innovators could commence litigation (if at all) from a position of knowledge. *See July 2009 House Hearing* at 8-9 (statement of Rep. Anna Eshoo) (the bill's "simple, streamlined patent resolution process" was an important means of preserving innovators' intellectual property rights); *id.* at 196 (statement of Teresa Stanek Rea) ("[I]t is essential that [the legislation] contain a patent enforcement mechanism that preserves the value of intellectual property by including . . . a timely and confidential information exchange between patent owners and the biologic follow-on companies."); *Emerging Health Care Issues: Follow-On Biologic Drug Competition: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 111th Cong. 17 (2009) (statement of Rep. Marsha Blackburn) (worrying about the "uncertainty that would be placed on our innovators" if there were no process for pre-launch patent litigation); *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 110th Cong. 85 (2007) (statement of Dr. David Schenkein) ("Any follow-on biologics

regulatory pathway should ensure that patent challenges are litigated or otherwise resolved prior to marketing approval of the follow-on product, in order to protect the innovator's intellectual property rights . . . .").

At the end of the day, the statute depends on a carefully crafted *quid pro quo*, wherein the biosimilar applicant can piggyback off of the innovator's hard work and investments, but has certain responsibilities and obligations in exchange. Biosimilar applicants like Sandoz "opt in" when they choose to benefit from the abbreviated procedures for approval, utilizing the innovators' data to do so; they cannot later "opt out" of the aspects that they disfavor, to the detriment of the companies that created the products in the first place. *See Celltrion Healthcare Co. v Kennedy Trust for Rheumatology Research*, No. 14 Civ. 22546 (PAC), 2014 WL 6765996, at *5 (S.D.N.Y. Dec. 1, 2014) (an applicant's "attempt[] to skirt the BPCIA's dispute resolution mechanisms while reaping the benefits of its approval process is improper").

II. THE BPCIA DOES NOT PREEMPT AMGEN'S STATE-LAW CLAIMS[4]

Under California law, "unfair competition" includes any "business act or practice" that is "unlawful." Cal. Bus. & Prof. Code § 17200; *Cel–Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 973 P.2d 527, 539 (Cal. 1999). "[A] business practice is unlawful [under California's Unfair Competition Law ("UCL")] 'if it is forbidden by any law,'" including federal law. *Olszewski v. Scripps Health*, 69 P.3d 927, 947 (Cal. 2003) (citation omitted); *Rose v. Bank of Am., N.A.*, 304 P.3d 181, 183 (Cal. 2013); *Cel-Tech*, 973 P.2d at 539. The UCL "'"borrows" violations of other laws and treats them as unlawful practices' that the unfair competition law makes independently actionable." *Cel-Tech*, 973 P.2d at 539-40 (quoting *State Farm Fire & Cas. Co. v. Superior Court*, 53 Cal. Rptr. 2d 229, 234 (Ct. App. 1996)).

If the BPCIA's notice-and-exchange provisions are mandatory, then failure to comply with those provisions is "unlawful" under the UCL. Neither the district court nor Sandoz has suggested otherwise. Instead, the district court concluded, without any analysis, that "[35] U.S.C. § 262(*l*)(9) sets out the exclusive

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[4] Amgen asserts two state-law claims: violation of California's Unfair Competition Law ("UCL") and conversion. *See* Complaint at 28-34, *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741 (N.D. Cal. Oct. 24, 2014), ECF No. 1. While this discussion focuses on the UCL claim, neither claim is preempted because the BPCIA does not preempt state law.

consequence for an applicant who elects not to provide its [application] and/or manufacturing information, or participate in any aspect of subsection (*l*)'s disclosure and negotiation process." A18. The district court's conclusion is wrong as a matter of both federal and state law.

A. Under California Law, UCL Remedies Are Cumulative To Any "Remedies" Provided By The BPCIA

Under California law, the UCL "is meant to provide remedies cumulative to those established by other laws, absent express provision to the contrary." *Rose*, 304 P.3d at 187 (citing Cal. Bus. & Prof. Code § 17205). Indeed, California courts "have long recognized that the existence of a separate statutory enforcement scheme does not preclude a parallel action under the UCL." *Id.* (citing *Stop Youth Addiction, Inc. v. Lucky Stores, Inc.*, 950 P.2d 1086, 1098-99 (Cal. 1998)). UCL remedies are not available only if the underlying "statute itself provides that the remedy is to be exclusive." *State v. Altus Fin., S.A.*, 116 P.3d 1175, 1187 (Cal. 2005); *Blue Cross of Cal., Inc. v. Superior Court*, 102 Cal. Rptr. 3d 615, 627 (Ct. App. 2009) ("[I]n order for a statute to deprive the city attorney of authority to sue under the UCL . . . , it must do so *expressly*.").[5]

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[5] In *Loeffler v. Target Corp.*, 324 P.3d 50 (Cal. 2014), the California Supreme Court held that a UCL suit was preempted by a state statutory scheme where the exclusiveness of the remedial scheme was not express. In that case, however, the court's interpretation of a sales tax statute was driven by the constitutional avoidance canon and the fact that the state constitution had provided

Although the district court here ruled that subsection (*l*)(9) sets forth the "exclusive consequence" for noncompliance, it did not identify any support in the statute for its conclusion, nor did it address controlling California law on this issue. *Cf. Altus Fin.*, 116 P.3d at 1187 (UCL relief barred because the statute provided that "'the commissioner, *exclusively* and except as otherwise expressly provided by this article . . . [m]ay . . . prosecute and defend any and all suits and other legal proceedings'" (emphasis altered) (citation omitted)). The BPCIA does not expressly provide an *exclusive* remedy. Moreover, subsection (*l*)(9) cannot even fairly be described as a "remedy" for failing to comply with the notice-and-exchange provisions. *See* Amgen Br. 55-57. At best, subsection (*l*)(9)(B) and (C) lift a "limitation" on a declaratory judgment action in certain circumstances.

B. The BPCIA Does Not Preempt Amgen's State-Law Claims

If the BPCIA notice-and-exchange provisions are mandatory (and they are), and if a UCL claim is available under state law (and it is), the only remaining question is whether that state-law claim is preempted by the BPCIA. Again, the

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that "tax refund issues may be litigated solely according to the procedure specifically provided in the tax code." *Id.* at 60. The desire to avoid constitutional doubts—combined with the fact that the tax code had erected a "comprehensive administrative scheme" to resolve tax questions by delegating authority to the Tax Board and by requiring taxpayers to exhaust administrative procedures before resorting to court—demonstrated that a UCL remedy was not available. *Id.* at 61-62. The BPCIA is entirely distinguishable; constitutional avoidance is not at issue here and no administrative agency has been charged with enforcement.

district court failed to engage in the required inquiry and, instead, speculated that "Congress intended . . . a self-contained statutory scheme under the BPCIA," rather than a "hunt . . . through the laws of the fifty states." A8 n.4. But the district court has the analysis backwards: Congress does not authorize or approve state-law claims, and it can preempt state law only in limited circumstances. There is no federal preemption here.

"'[T]he purpose of Congress is the ultimate touchstone in every pre-emption case.'" *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (citation omitted). The BPCIA contains no express preemption provision. Nor does federal patent law preempt the entire field of unfair competition. *See Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1333 (Fed. Cir. 1998) ("[T]here is no field preemption of state unfair competition claims that rely on a substantial question of federal patent law."), *overruled on other grounds*, *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999).

Although courts may also find preemption when a state law conflicts with or poses "an 'obstacle to the accomplishment and execution'" of federal objectives, *Wyeth*, 555 U.S. at 577 (citation omitted); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996), allowing a UCL claim to go forward in Amgen's case does neither. "The patent laws will not preempt [state-law] 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." *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1306 (Fed. Cir. 1999).[6] Amgen's state-law claims offer no "patent-like protection." Nor do they replicate a "federal patent law cause of action." The district court did not suggest otherwise.

Moreover, allowing an innovator to enforce the mandatory notice-and-exchange provisions through UCL claims would further Congress's intent of streamlining patent disputes in advance of product launch, not frustrate it. *See, e.g.*, *Ontiveros v. Zamora*, No. 08-cv-567, 2014 WL 3057506, at *3-4 (E.D. Cal. July 7, 2014) (no conflict preemption because UCL claim consistent with "animating purpose and objectives" of federal law); *Aguayo v. Oldenkamp Trucking*, No. 04-cv-6279, 2005 WL 2436477, at *9-10 (E.D. Cal. Oct. 3, 2005) (same). An innovator's claim is not premised on any conduct otherwise *permitted* by federal law. *Cf. Martinez v. Wells Fargo Home Mortg., Inc.*, 598 F.3d 549, 556-57 (9th Cir. 2010) (UCL claim preempted because would punish banks for conduct specifically allowed by federal scheme). Nor would it require a court to answer any legal question that the BPCIA has delegated to an administrative agency. *Cf. id.* at 556 ("regulation of a national bank's adherence to . . .

[6] Claims directed to conduct before the U.S. Patent and Trademark Office are preempted, *see, e.g.*, *Abbott Labs. v. Brennan*, 952 F.2d 1346, 1357 (Fed. Cir. 1991), but this case presents no such claim.

regulations is within the exclusive purview of" federal agency); *In re Cal. Wholesale Elec. Antitrust Litig.*, 244 F. Supp. 2d 1072, 1078, 1083 (S.D. Cal. 2003) ("Plaintiff's state-law claims . . . would inevitably conflict with [federal agency's] exclusive jurisdiction . . . ."), *aff'd sub nom., Pub. Util. Dist. No. 1 of Snohomish Cnty. v. Dynegy Power Mktg., Inc.*, 384 F.3d 756 (9th Cir. 2004). In sum, there is no basis to find that the UCL claim at issue here is preempted by the BPCIA.[7]

[7] As the district court correctly noted, the question whether there is a private right of action directly under the BPCIA for failing to comply with the notice-and-exchange provisions is not before this Court. *See* A8 n.4. Amgen's claims arise exclusively under state law, and whether there is also a private right of action under federal law is irrelevant. Indeed, courts have rejected the argument that UCL claims are preempted even when a federal right of action was indisputably unavailable. *See, e.g.*, *Rose*, 304 P.3d at 186 ("It is settled that a UCL action is not precluded 'merely because some other statute on the subject does not, itself, provide for the action or prohibit the challenged conduct.'" (citation omitted)); *In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1180 (Cal. 2008) ("[I]t is undisputed that section 337 [of the Federal Food, Drug, and Cosmetic Act ("FDCA")] bars private enforcement of the FDCA . . . . However, plaintiffs do not seek to enforce the FDCA. Their action is based on the violation of *state law* . . . .").

CONCLUSION

This Court should hold that the BPCIA notice-and-exchange provisions are mandatory, that a failure to comply with those provisions is unlawful, and that Amgen's state-law claims are not preempted by the BPCIA.

April 13, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 13, 2015, I caused a copy of the foregoing Corrected Brief for AbbVie Inc. as *Amicus Curiae* Supporting Plaintiffs-Appellants to be served by electronic means through the Court's CM/ECF system on counsel for all parties, who are registered CM/ECF users.

/s/ *Melissa Arbus Sherry*
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CERTIFICATE OF COMPLIANCE WITH RULE 32

1. I certify that this brief complies with the type-volume limitations of Fed. R. App. P. 29(d) and 32(a)(7)(B) because it contains 6,286 words, excluding the parts exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b).

2. I further certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally-spaced typeface using Microsoft Office Word in Times New Roman 14-point font.

April 13, 2015

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