No. 15-1195

IN THE
Supreme Court of the United States

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,
Cross-Petitioners,

v.

SANDOZ INC.,
Cross-Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR AMGEN INC. AND AMGEN MANUFACTURING LIMITED

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CORPORATE DISCLOSURE STATEMENT

The corporate disclosure statement included in Amgen's opening brief remains accurate.

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Sandoz continues to treat the BPCIA's mandatory, integrated procedures for the resolution of patent disputes like an à la carte menu from which it can pick and choose. But Congress did not craft an exceedingly detailed framework, providing that the sponsor and applicant "shall" fulfill each step, so that applicants could ignore it at will. Had Congress meant to make the framework optional, as it did in some earlier bills, it would have said so.

Sandoz's argument in response to the cross-petition is that, when Congress specified that a biosimilar applicant "shall" provide its application and manufacturing information to the reference product sponsor, 42 U.S.C. §262(*l*)(2)(A), it meant only that the applicant "shall" do so *if* it "wishes to engage in the information exchange" prescribed by §262(*l*). Sandoz Br. 35. That is a surpassingly strange interpretation of the word "shall." As the statute specifies, the applicant's real choice comes when it decides whether to follow §262(a)'s regular pathway to approval or take advantage of §262(k)'s streamlined pathway, which allows it to save hundreds of millions of dollars and years in development by relying on the sponsor's safety and efficacy data. If an applicant avails itself of the streamlined pathway, it must proceed with the process Congress mandated. 42 U.S.C. §262(*l*)(1)(B)(i) ("When a subsection (k) applicant submits an application under subsection (k), such applicant *shall provide* … the information required to be produced pursuant to paragraph (2)[.]" (emphasis added)).

Sandoz insists that Congress turned "shall" into "may" when it preserved the sponsor's patent rights even if the applicant fails to comply with §262(*l*)(2)(A). 35 U.S.C. §271(e)(2)(C)(ii); 42 U.S.C. §262(*l*)(9)(C). That argument vastly overreads the provisions in question,

which serve merely to avoid incoherent cross-references to other statutory provisions—not to create an entirely separate dispute-resolution pathway. Section 271(e)(2)(C)(ii) recognizes that the set of patents implicated in an artificial-infringement action (patents listed under §262(*l*)(3)) could otherwise contain no patents if the applicant breached §262(*l*)(2)(A), because the exchange of patent lists would not be triggered. It therefore allows suit on patents that *could* be listed if the applicant complied with §262(*l*)(2)(A). Section 262(*l*)(9)(C) makes a similar adjustment to preserve the limits that §262(*l*)(9)(A) and (B) would have placed on the applicant had it complied with §262(*l*)(2)(A), while clarifying that the sponsor retains its preexisting right to bring a declaratory-judgment action under 28 U.S.C. §2201. Neither provision remedies the harm caused to the sponsor by the applicant's breach, as they both leave the sponsor unable to identify in a timely and reliable manner which of its patents would be infringed. Neither, therefore, provides any basis to conclude that Congress intended to offer applicants that have chosen to file under the §262(k) pathway a *further* choice whether or not to comply with the disclosure requirement.

Indeed, it is nonsensical to suggest that, whenever Congress specifies some consequences of a statutory violation, it transforms the violation into a permissible choice. For example, if a statute states that a manufacturer "shall" not emit certain pollutants and may be fined if it does, no one would deny that a polluter (even one that pays the fine) is breaking the law. When Sandoz chose to take advantage of the §262(k) pathway while ignoring Congress's command that it "shall" provide Amgen with its application and manufacturing information, it similarly broke federal law, and conse-

quently is engaging in an "unlawful … business act or practice" in violation of California's Unfair Competition Law, Cal. Bus. & Prof. Code §17200.

Although the Court need not decide whether federal law authorizes orders enforcing §262(*l*)(2)(A), because Amgen sought such relief under state law, courts plainly may issue such orders in the course of adjudicating an infringement or declaratory-judgment action properly brought by the sponsor. Sandoz admits the sponsor can obtain the application and manufacturing information through discovery in such an action. It makes no sense, then, for Sandoz to suggest (at 21-22) that an order compelling the applicant to provide the required information is "entirely different" from adjudicating the underlying infringement claim.

Sandoz's interpretation would make a hash of the orderly path to resolution of patent disputes that Congress created. If the parties follow the steps set forth in §262(*l*), they can resolve their disputes in an efficient, sensible way. The applicant's early disclosure of its application and manufacturing information permits the sponsor to determine the set of patents implicated by the biosimilar—something that can vary widely even across biosimilars of the same reference product. The subsequent exchanges enable the parties to narrow their disputes, and streamline any necessary litigation, through early disclosure of the parties' contentions.

In place of that orderly process, Sandoz offers only complications and uncertainty. Under Sandoz's view, a sponsor may never even learn that an application has been filed. And if the sponsor does learn as much, it may lack sufficient information about the applicant's proposed product, uses, and manufacturing processes to know which patents may be infringed, and sufficient

information about the identity of the applicant and its affiliates to know whom and where to sue. Sandoz would have the sponsor bring suit on its best guess, include any conceivably relevant patent, and request the application and manufacturing information in discovery. Whether or not that would work, it would constitute an astonishing waste of resources for courts and litigants when compared with the alternative of simply requiring the applicant to obey §262(*l*)(2)(A).

If the Court holds that parties must take the steps Congress provided they "shall" take, the statute will work as Congress intended. If the statute's mandates are instead treated as a menu of options, Congress's carefully crafted system will be continually challenged and evaded, spawning extensive litigation. This Court should not discard Congress's coherent and comprehensive scheme in favor of Sandoz's stumbling-in-the-dark, anything-goes approach.

I. APPLICANTS MUST PROVIDE SPONSORS WITH THEIR APPLICATIONS AND MANUFACTURING INFORMATION

A. The Text Requires Disclosure

1. The statutory text specifies that the applicant "*shall* provide" its application and manufacturing information to the sponsor "[n]ot later than 20 days" after the FDA accepts the application for review. 42 U.S.C. §262(*l*)(2)(A) (emphasis added). The word "shall" indicates a mandatory command. Amgen Br. 58-60. That should be the end of the matter.

Sandoz argues (at 34-35) that the applicant's disclosure obligation becomes "mandatory" only if the applicant chooses to participate in the information-exchange process. That interpretation improperly writes into the statute a new prefatory clause: "[*I*]*f an applicant*

wishes to engage in the information exchange, it 'shall' timely provide its application." Sandoz Br. 35 (some emphasis added). Congress included no such clause in the statute.

Any conceivable ambiguity is erased by §262(*l*)(1)(B)(i), the first place in §262(*l*) where the disclosure requirement is mentioned. As that provision makes clear, the applicant's §262(*l*)(2)(A) obligation is triggered by its choice to pursue FDA approval under §262(k)'s streamlined pathway instead of §262(a)'s standard pathway:

> *When a subsection (k) applicant submits an application under subsection (k)*, such applicant *shall provide* to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to *the information required to be produced pursuant to paragraph (2)* and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate[.]

(Emphases added.) Having chosen to submit a §262(k) application, an applicant has no further choice about whether to comply with §262(*l*)'s information-exchange process.

Other provisions reinforce that construction. Amgen Br. 58-59. For example, Congress's repeated references to the applicant's "fail[ure]" to provide the "required" §262(*l*)(2)(A) information underscore the mandatory nature of the obligation. 35 U.S.C. §271(e)(2)(C)(ii); 42 U.S.C. §262(*l*)(9)(A), (C). Sandoz responds (at 37) by noting §262(*l*)(4)(B)'s reference to the parties' "fail[ure] to agree" on a list of patents for phase-one litigation. But that provision at most establishes that Congress's use of "fail" did not *create* an ob-

ligation to reach agreement where the statute requires only "good faith negotiations." 42 U.S.C. §262(*l*)(4)(A). The obligation to obey §262(*l*)(2)(A) is created not by the word "fail" but by the phrase "shall provide." The statute's references to the applicant's "fail[ure]" to do what is "required" by §262(*l*)(2)(A) simply confirm that Congress used "shall" in its ordinary, mandatory sense.

2. Sandoz points to several supposedly optional uses of "shall," to suggest that Congress meant "shall" in an optional sense here as well. None of Sandoz's arguments is persuasive.

Sandoz first invokes (at 35) a provision stating that the sponsor "shall bring an action for patent infringement" within 30 days of the parties' exchange of their patent lists. 42 U.S.C. §262(*l*)(6). Separate provisions specify that if a sponsor fails to bring the §262(*l*)(6) action within 30 days with respect to a listed patent, the "sole and exclusive remedy" that a court can grant for infringement is a reasonable royalty, in effect foreclosing injunctive relief or lost profits on that patent. 35 U.S.C. §271(e)(6)(A)(ii)(I), (B). Sandoz assumes from those provisions that a sponsor that fails to file a timely action cannot be said to "'violate'" any mandatory obligation. Sandoz Br. 35. But Sandoz offers no basis for that incorrect conclusion. If the applicant has fulfilled its obligations up to that point, the statute provides that a sponsor *must* file a §262(*l*)(6) action within the specified time.[1]

[1] It is unlikely that the applicant would seek an order enforcing §262(*l*)(6). If a sponsor fails to comply with §262(*l*)(6), it primarily burdens its *own* rights by limiting its remedy for infringement. Applicants are unlikely to complain about that narrowing of the sponsor's potential remedies, especially since applicants retain

Sandoz also invokes (at 37-38) statutes and rules stating that an appeal "shall" be taken by a particular date. For example, 28 U.S.C. §2101(a) states that "[a] direct appeal to the Supreme Court … shall be taken within thirty days after the entry of the interlocutory or final order, judgment or decree." But that statute (and similar provisions) use the passive voice to indicate that *any* appeal shall be taken within the specified period—not that the losing party in the lower court *must* take an appeal. The statute would have an entirely different meaning if it affirmatively required, much as §262(*l*)(2)(A) does, that the losing party "shall appeal" the judgment "within thirty days." *See also infra* pp. 13-14 (party may waive only provision meant for its benefit, not opponent's benefit).

In short, nothing in the text supports Sandoz's argument that applicants that avail themselves of §262(k) thereafter may choose whether to comply with §262(*l*)(2)(A) or any of the other requirements set forth in the BPCIA's detailed dispute-resolution scheme. Where Congress wanted to give the applicant discretion, it said so. *E.g.*, 42 U.S.C. §262(*l*)(1)(B)(i) (con-

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the right to obtain patent certainty by filing a declaratory-judgment action on phase-one patents. By contrast, an applicant's violation of §262(*l*)(2)(A) primarily burdens the *sponsor*. *See infra* pp. 13-14 (discussing principle that one party cannot waive a statutory provision intended for the benefit of another party).

Sandoz's argument (at 35) regarding constitutional concerns with enforcing §262(*l*)(6) strays even further into the realm of the theoretical. Even had Sandoz substantiated the argument, it would provide no reason to hold that the provisions actually before this Court are not mandatory or cannot be enforced. Notably, Sandoz does not claim that enforcing the provisions at issue here would raise any constitutional concerns.

trasting the materials that "shall" be provided under §262(*l*)(2)(A) with "any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate"); *id.* §262(*l*)(2)(B) (applicant "may provide … additional information requested by" the sponsor); *id.* §262(*l*)(1)(A) (parties may agree to alternative confidentiality rules). In contrast, Congress repeatedly and exclusively spoke in mandatory terms when it established the requirement at issue here.

B. The BPCIA's History And Purpose Make Clear That §262(*l*)(2)(A) Requires Disclosure

As Amgen's opening brief explains (at 60-64), Congress enacted §262(*l*) to ensure sponsors would have a meaningful opportunity to protect their patent rights before a biosimilar's launch. Sandoz's interpretation of §262(*l*)(2)(A) cannot be reconciled with that objective.

Were Sandoz right that an applicant could unilaterally deny the sponsor the information Congress directed it to provide, the sponsor could not meaningfully assess its patents, engage in informed pre-suit licensing discussions or other attempts to avoid litigation, or obtain a mandatory injunction against infringement through a suit under §262(*l*)(6). The sponsor's only way to protect its patent rights would be to file an infringement action—likely on information and belief, and likely including dozens or hundreds of conceivably relevant patents—without actually knowing which of its patents the biosimilar would infringe. That is not what Congress intended in creating a *streamlined* dispute-resolution process.[2]

[2] As Amgen's opening brief explains (at 67-72), Sandoz's position on §262(*l*)(8)(A) exacerbates these concerns by creating the

1. Sandoz relies heavily (at 38) on 35 U.S.C. §271(e)(2)(C), which makes the submission of a biosimilar application an act of infringement whether or not the applicant complies with §262(*l*)(2)(A). Sandoz seems to assume (at 38) that a sponsor would *prefer* the applicant to violate §262(*l*)(2)(A) because it then "gains far more control over the scope and timing of any infringement suit" and "can sue immediately on all its patents." That is utterly wrong.

As an initial matter, if the applicant refuses to comply with §262(*l*)(2)(A), the sponsor may not even learn that an application has been filed (let alone that the FDA has accepted it for review). Any right to sue for infringement is meaningless if the applicant's infringement remains hidden or its detection obscured or delayed by the applicant's violation of §262(*l*)(2)(A). Sandoz downplays this concern, arguing that sponsors can scour "public information about biosimilar development." Sandoz Br. 3; *see id.* at 17. But as Amgen's opening brief explains (at 69-70), securities disclosures, clinical trial databases, and the like are insufficient to ensure access to the information that Congress explicitly provided sponsors should have. Sandoz offers no response.

If a sponsor learns that an application has been filed, despite a §262(*l*)(2)(A) violation, Sandoz expects the sponsor to "sue immediately on *all* its patents." Sandoz Br. 38 (emphasis added). No sponsor would prefer such a blind, burdensome proceeding to the informed, well-ordered proceedings prescribed by §262(*l*). Biologics are enormously complex molecules

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possibility that a sponsor will be unaware of the biosimilar before launch.

manufactured in living organisms. Amgen Br. 6-11. A biologic's structure and composition depends on its manufacturing process. *Id.* And the manufacturing process can include complex steps: developing cell lines, expanding and culturing the cells, removing any impurities, deactivating viruses, and so forth.[3] A sponsor's portfolio might include dozens or hundreds of patents that relate to these steps and thus *could* be implicated by the applicant's process. *E.g.*, CAJA472 (explaining classes of patents owned by Amgen that related, *e.g.*, to "purification of protein"). If the sponsor does not sue on all such patents, it may risk losing the opportunity to assert them at all, as Amgen's experience in the *Hospira* case makes evident. Amgen Br. 61-62.[4] It may likewise have to sue on every potentially relevant product and method-of-use patent, without knowing anything about the specific structure or formulation of the biosimilar or the uses for which the applicant seeks approval, simply to learn whether there is a factual basis to assert the patents. It is absurd to think a spon-

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[3] Conner et al., *The Biomanufacturing of Biotechnology Products, in Biotechnology Entrepreneurship* 351, 355 (Shimasaki ed., 2014).

[4] Sandoz's response to *Hospira* (at 41 n.7) misses the point. Amgen sought discovery on patents that were absent from the §262(*l*)(3) lists only because Hospira declined to provide its manufacturing information as required by §262(*l*)(2)(A), leaving Amgen unable to determine which manufacturing-process patents could reasonably be asserted. Appellant's Br. 10, Dkt. 28, No. 2016-2179 (Fed. Cir. Sept. 12, 2016). If the Federal Circuit affirms the denial of discovery, Amgen and other sponsors will have no choice in future cases but to blindly file suit on every potentially relevant patent, even though most will ultimately prove irrelevant because the applicant is not using the particular processes claimed in the patents.

sor—not to mention Congress or the courts—would prefer this inefficient outcome to §262(*l*)'s procedures, which guarantee the sponsor access to the applicant's product and process information at the outset of the dispute-resolution process and allow the parties to narrow the dispute to what is actually relevant.[5]

2. Sandoz also suggests (at 40) that, in enacting §271(e)(2)(C)(ii), Congress must have thought a sponsor would have enough information even without the §262(*l*)(2)(A) disclosures to determine which patents were infringed. That is incorrect. Congress was well aware of the complexity of biologics, the inevitable differences between the reference product and the biosimilar, and the importance of the specific manufacturing process used for each product. 155 Cong. Rec. E7683 (2009) (a biologic "is unique to the cell lines and specific process used to produce it" (statement of Rep. Eshoo)); *see also* Amgen Br. 9. None of the relevant product or process details is available from public sources. That is why Congress intended the sponsor to use the §262(*l*)(2)(A) information to "determin[e] … whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation" of the biosimilar. 42 U.S.C. §262(*l*)(1)(D).

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[5] Equally meritless is Sandoz's suggestion (at 38-39) that a sponsor would prefer to "forc[e] the applicant to launch its product" without patent certainty. Amgen has explained the price erosion and other irreparable harm sponsors face when a competitor's infringing product floods the market. *E.g.*, Amgen Br. 41; C.A. Dkt. 55 at 16-19; *see also* Professors' Br. 17-19. No sponsor would willingly risk such irreparable harm.

Sandoz's argument misunderstands the reason Congress enacted §271(e)(2)(C)(ii). The provision is simply a fail-safe to ensure that the applicant cannot entirely stall the dispute-resolution process by refusing to provide the required disclosures. It does not make the violation of §262(*l*)(2)(A) an act of infringement. Rather, the *submission* of a §262(k) application is the artificial act of infringement. The patents deemed infringed include any listed under §262(*l*)(3)(A) if the applicant complies with §262(*l*)(2)(A). 35 U.S.C. §271(e)(2)(C)(i). And if the applicant does not comply, the patents deemed infringed by the applicant's submission include any that the sponsor *could* list under §262(*l*)(3)(A). *Id.* §271(e)(2)(C)(ii). This fail-safe provision is not a distinct, alternative dispute-resolution pathway; it is simply an adjustment to the §262(*l*) pathway to avoid the anomaly that would occur if there were no §262(*l*)(3)(A) list by virtue of the applicant's failure to provide the §262(*l*)(2)(A) information. That Congress contemplated that a sponsor might be forced to sue without the §262(*l*)(2)(A) information in no way indicates that Congress considered such an outcome remotely desirable or an acceptable "choice" that the applicant can make in lieu of following §262(*l*)(2)(A)'s mandate. Section 271(e)(2)(C)(ii) expressly and simply establishes that the submission of a biosimilar application is an act of infringement whether or not the applicant complies with §262(*l*)(2)(A)'s mandate—nothing more.

3. Sandoz's view would also allow infringing applicants unilaterally to limit a sponsor's remedies for infringement. Where a sponsor within the 12-year data exclusivity period prevails on "an action for infringement … under section [262](*l*)(6)," 35 U.S.C. §271(e)(4)(D) provides that "the court *shall order* a

permanent injunction prohibiting any infringement of the patent" until it expires. (Emphasis added.) If the applicant could choose not to follow the steps set forth in §262(*l*), thus precluding a §262(*l*)(6) action, it would improperly cut off the sponsor's access to a mandatory permanent injunction.

Sandoz's responses are meritless. It first suggests (at 42) that treating the injunction as mandatory is inconsistent with *eBay Inc.* v. *MercExchange, LLC*, 547 U.S. 388 (2006). But *eBay* requires a court to apply the traditional four-factor test when exercising its *equitable discretion* whether to grant injunctive relief, *id.* at 391-392; it does not apply to statutorily mandated injunctions like the one prescribed by §271(e)(4)(D). That distinction also answers Sandoz's next argument: Although a *discretionary* injunction remains available under §271(e)(4)(B), Sandoz would deny the sponsor the certainty of mandatory injunctive relief. And although Sandoz notes (at 43) that Amgen was ineligible for a mandatory injunction, because a sponsor can obtain that remedy only if the biologic's 12-year exclusivity period has not yet passed, that is irrelevant. The availability or unavailability of the injunction in this particular case is no reason to adopt Sandoz's erroneous interpretation as the standard governing all future cases.

As Judge Newman recognized below, Pet. App. 41a, Sandoz's position would allow an applicant to decide for itself whether to comply with provisions—like §262(*l*)(2)(A) and §262(*l*)(8)(A)—that are meant primarily for the *sponsor*'s benefit. A party can waive compliance with a statutory or contractual provision if the provision is "intended for *his* benefit." *Shutte* v. *Thompson*, 82 U.S. (15 Wall.) 151, 159 (1873) (emphasis added); *see also United States* v. *Mezzanatto*, 513 U.S. 196, 200-201 (1995). A party can, for example, waive its

right to appeal an adverse judgment because doing so works only to its detriment. *Cf.* Sandoz Br. 37-38; *supra* p. 7. But a party "cannot waive or disregard a provision that benefits those in an adverse position." Pet. App. 41a (Newman, J., concurring in part and dissenting in part). That is what Sandoz seeks to do. Section 262(*l*)(2)(A) protects the *sponsor*'s rights to assert all relevant patents and obtain a mandatory injunction if warranted. Applicants cannot unilaterally treat compliance with §262(*l*)(2)(A) as optional simply because they regard the possibility of an immediate, blunderbuss infringement action as more "expedien[t]," Sandoz Br. 42.

4. Finally, Sandoz nowhere disputes that its proposed interpretation would reinstate precisely the approach Congress rejected year after year during the biosimilars debates: a scheme giving the applicant discretion whether to participate in any patent-dispute resolution process prior to launch. *See* Amgen Br. 63-64; BIO Br. 21-22 & n.7; Professors' Br. 32-36. Sandoz makes the unremarkable point (at 43) that congressional inaction can be unpersuasive evidence of congressional intent. But this Court has previously looked to closely related bills considered and rejected by Congress to inform the meaning of the statute ultimately enacted. *See, e.g.*, *Arizona* v. *United States*, 132 S. Ct. 2492, 2504 (2012); *Hamdan* v. *Rumsfeld*, 548 U.S. 557, 579-580 (2006); *Trbovich* v. *United Mine Workers of Am.*, 404 U.S. 528, 532-535 (1972). Here, some Members of Congress and stakeholders advocated for an optional dispute-resolution scheme, but Congress imposed a mandatory one instead. Sandoz seeks to rewrite the BPCIA to replace the position that prevailed with the one that lost.

II. COURTS MAY ORDER APPLICANTS TO COMPLY WITH THE DISCLOSURE REQUIREMENT

Sandoz errs in asserting that courts lack the power to order compliance with §262(*l*)(2)(A).

A. Amgen Sought An Injunction Under State Law

As Amgen's opening brief explains (at 64), this Court need not decide whether federal law authorizes orders to enforce §262(*l*)(2)(A) because Amgen sought such relief under California's Unfair Competition Law (UCL). Sandoz recognized as much in opposing certiorari. Opp. 2.

Sandoz accuses Amgen (at 44) of "fail[ing] to note" the supposed holding below that a UCL "injunction is unavailable on state law grounds." But the Federal Circuit did not say a UCL injunction is unavailable to enforce a mandatory duty created by §262(*l*)(2)(A). It held a UCL injunction was unavailable only on the theory that §262(*l*)(2)(A) does *not* create a mandatory duty. Pet. App. 27a. Amgen's cross-petition (at 25-39) and opening brief (at 58-64) dispute that erroneous holding and the Federal Circuit's reliance on it to dispose of the UCL claim.

The Court should also reject Sandoz's argument (at 44 n.9) that "any attempt to use California law to 'enforce' the [BPCIA] would be preempted and would in any event support an injunction only in California." Sandoz previously disavowed any preemption argument (*e.g.*, CAJA1854), and the Federal Circuit accordingly did not consider it. Pet. App. 26a n.5. This Court "ordinarily do[es] not consider claims that were neither raised nor addressed below," *Travelers Cas. & Sur. Co. of Am.* v. *Pacific Gas & Elec. Co.*, 549 U.S. 443, 455

(2007), much less ones expressly disavowed. In any event, Sandoz's newly minted and poorly developed argument lacks merit. *See* Amgen Br. 43; AbbVie Br. 19-25; U.S. Br. 12-16, *Bank of Am., N.A.* v. *Rose*, No. 13-662 (U.S. May 27, 2014), 2014 WL 2202864.

Moreover, the propriety of a nationwide injunction is not at issue here. Unlike in *Allergan, Inc.* v. *Athena Cosmetics, Inc.*, 738 F.3d 1350, 1358-1360 (Fed. Cir. 2013), which involved an injunction against the sale of a product anywhere in the United States, the act Amgen sought to require—Sandoz's provision of its application and manufacturing information—is a one-time occurrence, not a nationwide course of conduct. There is no doubt that the district court could lawfully have ordered Sandoz, a party subject to its jurisdiction, to perform that required act.[6]

B. Federal Law Authorizes Orders To Enforce The Disclosure Requirement

If the Court reaches the question whether federal law authorizes orders to enforce §262(*l*)(2)(A), it should answer that question in the affirmative.

1. As Amgen's opening brief explains (at 43-46, 64), it is irrelevant whether the BPCIA confers a private right of action to enforce §262(*l*)(2)(A). Cases on

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[6] Even if an order requiring compliance with §262(*l*)'s mandates could be construed as a nationwide injunction, it would be permissible because—unlike the injunction in *Allergan*—it would not "impose[] the UCL on entirely extraterritorial conduct regardless of whether the conduct in other states causes harm to California," 738 F.3d at 1358. The consequences of an applicant's breach of §262(*l*) cannot be limited to states outside California, and here, Sandoz's breach directly harmed Amgen, a California company.

private rights of action address when private litigants, rather than the government, may sue to enforce a statute or regulation that does not expressly afford them a cause of action. Here, the government plays no enforcement role, and no one doubts that sponsors have a right to sue applicants. The only question is whether, in a suit properly before it, the court may order the applicant to comply with its procedural obligations under the BPCIA. That question is answered by the presumption that federal courts possess equitable power to remedy violations of the law in cases properly before them. *Amgen Inc.* v. *Apotex Inc.*, 827 F.3d 1052, 1064 (Fed. Cir. 2016); Amgen Br. 45-46.

Sandoz mistakenly assumes (at 20-23, 44) that orders requiring compliance with §262(*l*) are unrelated to the infringement or declaratory-judgment actions that a sponsor may bring.[7] Sandoz is right that a court adjudicating a patent-infringement suit obviously could not, for example, order the defendant to comply with its pollution-control obligations. But orders requiring compliance with §262(*l*)'s procedural requirements are intimately related to infringement and declaratory-judgment actions, because they permit the efficient litigation and adjudication of such actions.

Consider Sandoz's account (at 40-41) of how a sponsor should proceed if, due to the applicant's failure to provide its application and manufacturing information, the sponsor lacks sufficient knowledge to determine which of its patents may be infringed. Sandoz would

[7] Sandoz's arguments about the enforceability of §262(*l*)(2)(A) (at 44) incorporate by reference its arguments about the enforceability of §262(*l*)(8)(A) (at 20-28). Amgen likewise addresses the latter in the course of responding to the former.

have the sponsor blindly sue for a declaratory judgment of infringement, then obtain the application and manufacturing information through "normal discovery tools." But if the sponsor can obtain the same materials in discovery, then it makes no sense for Sandoz to suggest that an up-front order requiring the applicant to comply with its statutory duty, avoiding the unnecessary rigmarole and delay of discovery, would somehow be unrelated to the underlying suit. Requiring the applicant to comply with §262(*l*)(2)(A) is not "entirely different" from adjudicating the underlying infringement claim, as Sandoz argues (at 21-22); it is part and parcel of the same enterprise.

Such orders fall well within the district courts' inherent authority "to manage their own affairs so as to achieve the orderly and expeditious disposition of cases," *Link* v. *Wabash R.R. Co.*, 370 U.S. 626, 630-631 (1962); *see also, e.g.*, *Chambers* v. *NASCO, Inc.*, 501 U.S. 32, 43-44 (1991); *Landis* v. *North Am. Co.*, 299 U.S. 248, 254 (1936). "There is universal acceptance in the federal courts that, in carrying out" its duty to "effectuat[e] the speedy and orderly administration of justice … , a district court has the authority to enter pretrial case management and discovery orders designed to ensure that the relevant issues to be tried are identified, that the parties have an opportunity to engage in appropriate discovery and that the parties are adequately and timely prepared so that the trial can proceed efficiently and intelligibly." *United States* v. *W.R. Grace*, 526 F.3d 499, 508-509 (9th Cir. 2008) (en banc). An order requiring the applicant to produce the information required by §262(*l*)(2)(A), to facilitate the efficient reso-

lution of patent-infringement claims, is a paradigmatic exercise of this authority.[8]

2. Even were the relevant question whether §262(*l*)(2)(A) supports a private right of action, the answer would be that it does.

The private-right-of-action analysis boils down to a simple question: Did Congress intend to enable private parties to enforce a statutory or regulatory requirement? Amgen Br. 50. Here, there is no federal enforcement of §262(*l*)(2)(A). As a result, the real question becomes whether Congress intended it to be enforceable at all. The answer is yes: Congress regarded §262(*l*)(2)(A) as a mandate, not a choice, *see supra* pp. 4-14, and a mandate that cannot be enforced is no mandate at all. It follows that Congress meant for §262(*l*)(2)(A) to be enforceable by private litigants.

Sandoz attacks (at 24) the notion "that when Congress regulates conduct between private parties, courts can invent causes of action and remedies." Amgen makes no such argument. The only fair inference from §262(*l*)'s text, structure, and purpose is that Congress *did* intend §262(*l*)(2)(A) to be enforceable by sponsors.

3. Finally, Sandoz renews its argument (at 33-34, 44) that courts cannot order compliance with §262(*l*)(2)(A) because other provisions—35 U.S.C. §271(e)(2)(C)(ii) and 42 U.S.C. §262(*l*)(9)(C)—allegedly state the exclusive consequences of non-compliance. As Amgen's opening brief explains (at 65-67), neither of those provisions remedies the harm caused by an applicant's breach of §262(*l*)(2)(A), and they should not be

[8] If additional authority were needed, it is supplied both by 35 U.S.C. §283 and by the All Writs Act, 28 U.S.C. §1651.

read to foreclose an order to comply with §262(*l*)(2)(A), which actually *would* remedy the harm.

Section 262(*l*)(9)(C) preserves the limits that §262(*l*)(9)(A) and (B) would have imposed on the applicant's ability to bring a declaratory-judgment action had it complied with §262(*l*)(2)(A). It also adjusts for the fact that §262(*l*)(9)(A)'s restrictions on both the applicant and the sponsor presuppose the existence of patent lists under §262(*l*)(3) and (4) or (5)(B), and therefore would be incoherent where such lists have not been created. *See* 42 U.S.C. §262(*l*)(9)(A) (applies to "any patent that is described in clauses (i) and (ii) of paragraph (8)(B)"); *id.* §262(*l*)(8)(B)(i)-(ii) (describing patents with reference to the §262(*l*)(3) and (4) or (5)(B) lists). At the same time, §262(*l*)(9)(C) clarifies that the sponsor retains its preexisting right to seek declaratory relief under 28 U.S.C. §2201 in appropriate cases—reinforcing that, by its plain terms, the restriction §262(*l*)(9)(A) places on a sponsor's right to bring a declaratory-judgment action is inapplicable when the applicant does not make the §262(*l*)(2)(A) disclosure. That preservation of the sponsor's background rights, combined with adjustments to avoid obsolete cross-references to patent lists the applicant has prevented from being created, was never intended to be an exclusive remedy for the applicant's breach.

Indeed, one must suspend disbelief to conclude that Congress intended §262(*l*)(9)(C) to remedy the harm caused by a §262(*l*)(2)(A) violation. Even on Sandoz's account, it could do so only through a convoluted chain of events. If the sponsor manages to learn that an application has been submitted, which is not guaranteed, then §262(*l*)(9)(C) confirms the sponsor can (1) file a declaratory-judgment action on *potentially* relevant patents, even though it lacks the information that would

allow it to determine which of its patents will be infringed and who the proper defendant would be; and (2) seek the application and manufacturing information in discovery, with all the attendant costs and complications, and with the risk that the district court may erroneously deny discovery (as occurred in the *Hospira* case, *see* Amgen Br. 61; *supra* p. 10 n.4). Even if this process eventually allows the sponsor to obtain the information to which it is entitled, that is likely to happen only after weeks or months of pointless delay. Here, for example, the statute entitled Amgen to receive Sandoz's application and manufacturing information by July 27, 2014, but Amgen did not obtain the application through discovery until February 9, 2015—108 days after filing suit and just 25 days before the FDA licensed Sandoz's biosimilar. Pet. App. 8a, 63a. This would be a bizarre way for Congress to have envisioned the enforcement of §262(*l*)(2)'s straightforward command that the applicant "shall provide" its application and manufacturing information within "20 days."

Sandoz is equally wrong to suggest that 35 U.S.C. §271(e)(2)(C)(ii) creates the exclusive remedy for a violation of §262(*l*)(2)(A). As explained above (at 12), a §262(*l*)(2)(A) violation is not an act of infringement. The *submission* of a §262(k) application is the act of infringement under either §271(e)(2)(C)(i), where the applicant complies with §262(*l*)(2)(A), or §271(e)(2)(C)(ii), where it does not. Section 271(e)(2)(C)(ii) simply alters the language of §271(e)(2)(C)(i), from "is identified" to "could be identified," to reflect the reality that there may be no patent list without §262(*l*)(2)(A) compliance. Section 271(e)(2)(C)(ii) can no more be regarded as an exclusive remedy for a violation of §262(*l*)(2)(A) than §262(*l*)(9)(C) can.

Moreover, statutes and rules often specify retrospective consequences of an unlawful act without foreclosing orders meant to prevent the unlawful act from occurring in the first place. No one would think, for example, that a court cannot issue an order forbidding the spoliation of electronically stored information in civil discovery simply because a procedural rule specifies certain consequences for spoliation. Nor would anyone think that a court could not order the parties to expedite an action under the Hatch-Waxman Act, simply because the statute also authorizes the court to extend the 30-month stay of market entry if the parties violate the mandate to "reasonably cooperate in expediting the action," 21 U.S.C. §355(j)(5)(B)(iii). Likewise here: Congress's decision to set forth certain retrospective effects of a §262(*l*)(2)(A) violation, none of which actually remedies the harm caused by the violation, does not preclude an order to comply with the requirement.

Finally, Sandoz's invocation of 35 U.S.C. §271(e)(4) (at 45) is a non sequitur. That provision circumscribes the "remedies which may be granted by a court for an act of infringement described in" §271(e)(2). But as Amgen's opening brief explains (at 66-67), a breach of §262(*l*)(2)(A) is not "an act of infringement."

* * *

The question presented may arise from a complicated statute, but the answer is ultimately straightforward: When Congress provides that a person "shall" do something, it is generally imposing a command, not offering a choice. That mandatory construction is reinforced where an opt-out construction would create absurd results. And it is doubly reinforced where complying with the mandate would be straightforward. The Court should reject Sandoz's contrary approach, which

would eviscerate the statutory scheme for no reason other than Sandoz's desire not to be bound by it.

CONCLUSION

The Federal Circuit's judgment on §262(*l*)(2)(A) should be reversed.

Respectfully submitted.

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