No. 16-1308

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

AMGEN INC. AND AMGEN MANUFACTURING LTD.,

Plaintiffs-Appellees,

v.

APOTEX INC. AND APOTEX CORP.,

Defendants-Appellants.

On appeal from the United States District Court for the Southern District of Florida, Case No. 15-61631-CIV-COHN/SELTZER, Judge James I. Cohn

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REPLY BRIEF FOR DEFENDANTS-APPELLANTS APOTEX INC. AND APOTEX CORP.

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INTRODUCTION

This case presents a specific issue that has not been addressed by this Court: whether the notice of commercial marketing provision of the Biologics Price Competition and Innovation Act ("BPCIA"), paragraph (*l*)(8)(A), is mandatory when a biosimilar applicant (here, Apotex) has chosen to participate in the disclosure requirements of 42 U.S.C. § 262(*l*)(2)(A). The answer is no.

1. Paragraph (*l*)(9)(B) contemplates that a biosimilar applicant that decides to participate in the disclosure requirements of paragraph (*l*)(2)(A) may choose not to provide a notice of commercial marketing under paragraph (*l*)(8)(A). Paragraph (*l*)(9)(B) provides that if the biosimilar applicant meets the disclosure requirements of paragraph (*l*)(2)(A) but chooses ***not*** to provide a notice of commercial marketing under paragraph (*l*)(8)(A)—as Apotex did here—then the reference product sponsor (here, Amgen) may bring an action for declaratory judgment. Put another way, paragraph (*l*)(9)(B) provides the sponsor with its remedy if an applicant like Apotex, who first engages in the disclosure requirements of paragraph (*l*)(2)(A), later chooses not provide a notice of commercial marketing under paragraph (*l*)(8)(A).

This reading of the statute is fully consistent with this Court's decision in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015). There, this Court held that the information disclosure requirements of paragraph (*l*)(2)(A) were not

mandatory because other parts of the statute, including paragraph (*l*)(9)(C), provided the exclusive remedy in the event that the applicant decided not to disclose the pertinent information. *Sandoz*, 794 F.3d at 1355-56. The Court also held that, for applicants who elect not to make the paragraph (*l*)(2)(A) information disclosures, the notice of commercial marketing of paragraph (*l*)(8)(A) is mandatory because there is no corresponding provision of the statute that sets forth the remedy for noncompliance. *Id.* In particular, paragraph (*l*)(9)(B), which provides such a remedy for applicants who *do* disclose the paragraph (*l*)(2)(A) information, *does not apply* to applicants (like Sandoz) who *do not* make the information disclosure.

In the present case, Apotex made the paragraph (*l*)(2)(A) information disclosures; therefore, paragraph (*l*)(9)(B) prescribes the remedy if Apotex elects not to provide the paragraph (*l*)(8)(A) notice of commercial marketing. Under the logic of *Sandoz*, in view of paragraph (*l*)(9)(B) and in order not to render that provision superfluous, this Court should construe paragraph (*l*)(8)(A) as non-mandatory for applicants like Apotex who comply with the information disclosures of paragraph (*l*)(2)(A).

2. Apotex's interpretation of the BPCIA comports with Congress's intent to only provide a reference product sponsor ("RPS" or "sponsor") with only 12 years of market exclusivity. In contrast, the district court's and Amgen's interpretation

would *always* lead to 12 ½ years of market exclusivity for the sponsor. Such a result is counter to Congress's intent and counter to this Court's prediction in *Sandoz* that "[t]hat extra 180 days will not likely be the usual case . . . ." *Sandoz*, 794 F.3d at 1358.

3. A compulsory notice of commercial marketing by a biosimilar applicant that provided a paragraph (*l*)(2)(A) disclosure is not in harmony with the statutory purposes of the BPCIA. Once the RPS has sued the biosimilar applicant in a paragraph (*l*)(6) litigation, as Amgen has done in this case, the RPS has the right to seek preliminary injunctive relief on the patents asserted in that litigation. Further, if a biosimilar applicant complies with the disclosure requirements of paragraph (*l*)(2)(A) but thereafter chooses not to provide a notice of commercial marketing, the one and only remedy for the RPS is to file a declaratory judgment action under paragraph (*l*)(9)(B).

Here, Amgen has already sued Apotex on all of the patents that it has identified as relevant to Apotex's proposed biosimilar pegfilgrastim product and obtained technical details about the product more than a year ago. Therefore, Amgen does not need an extra 180 days to assess its patent rights or to gain information about the accused product. Amgen's decision to seek an injunction based on Apotex's lack of a notice of commercial marketing, rather than on the

merits of Amgen's asserted patents, reflects an extra-textual attempt to obtain an undeserved extra 180 days of monopoly profits, which this Court should reject.

ARGUMENT

I. IF THE BIOSIMILAR APPLICANT PROVIDES PARAGRAPH (*l*)(2)(A) DISCLOSURES, THE BPCIA ALLOWS THAT THE NOTICE OF COMMERCIAL MARKETING IS NOT COMPULSORY

A. Paragraph (*l*)(9)(B) Expressly Contemplates that a Biosimilar Applicant that Provides Paragraph (*l*)(2)(A) Disclosures May Elect Not To Provide a Notice of Commercial Marketing

Paragraph (*l*)(9)(B) precisely spells out the consequences that flow from an applicant's decision not to provide the notice of commercial marketing called for in paragraph (*l*)(8)(A): "If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under . . . paragraph 8(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent" that the sponsor identified as relevant to the proposed biosimilar product in its paragraph (*l*)(3)(A) list, including any patents that were later added to the list under paragraph (*l*)(7), because they were licensed or obtained only after the list was initially compiled. The opening clause of the paragraph expressly contemplates that an applicant might decide not to "complete an action" required of the applicant "under paragraph (8)(A)." That opening sentence cannot be squared with Amgen's position that all applicants must comply with paragraph

(*l*)(8)(A) in all circumstances. On its face, the text contemplates what happens if an applicant decides not to give the paragraph (*l*)(8)(A) notice.

Furthermore, paragraph (*l*)(9)(A) provides important context for paragraph (*l*)(9)(B). Paragraph (*l*)(9)(A) states that "[i]f a subsection (k) applicant provides the application and information required under paragraph (2)(A)," then neither the sponsor nor the applicant may bring a declaratory judgment action concerning the patents that the parties have identified as relevant but that are not already in litigation under paragraph (*l*)(6). Paragraph (*l*)(9)(A) further provides that this bar on declaratory judgment actions is lifted when the applicant gives notice of commercial marketing under paragraph (*l*)(8)(A). As noted above, paragraph (*l*)(9)(B) provides that, if the applicant elects *not* to give the paragraph (*l*)(8)(A) notice of commercial marketing, then the declaratory judgment actions become available only to the RPS and not to the applicant. Paragraph (*l*)(9)(B) thus applies only to those applicants who have elected to make the disclosures under paragraph (*l*)(2)(A). And paragraph (*l*)(9)(B) plainly contemplates that if the biosimilar applicant meets the disclosure requirements of paragraph (*l*)(2)(A), then it may choose *not* to provide a notice of commercial marketing under paragraph (*l*)(8)(A).

Indeed, if the paragraph (*l*)(8)(A) notice were always mandatory, then there would be no reason for paragraph (*l*)(9)(B) to list paragraph (*l*)(8)(A) as one of the subsequent acts that a biosimilar applicant may fail to perform. Further, under the

district court's and Amgen's reading, the declaratory judgment penalty provision outlined in paragraph (*l*)(9)(B) is superfluous because it covers a situation that could never happen: if the paragraph (*l*)(8)(A) notice were required of every applicant in every case, then there would be no need for the statute to spell out the consequences of a decision not to give that notice.

In response to the point that its reading of the statute renders paragraph (*l*)(9)(B) superfluous, Amgen argues that the paragraph serves another purpose in preventing the biosimilar applicant from pursuing a declaratory-judgment action against the RPS where the biosimilar applicant chooses not to provide notice under paragraph (*l*)(8)(A). Red Br. at 46. That is incorrect. Paragraph (*l*)(9)(A), ***not*** paragraph (*l*)(9)(B), prevents the biosimilar applicant from pursuing a declaratory-judgment action against the RPS where the biosimilar applicant does not comply with paragraph (*l*)(8)(A). Indeed, under paragraph (*l*)(9)(B), the biosimilar applicant's rights are not affected; that is, if the biosimilar applicant fails to perform a "subsequent act," it still cannot file a declaratory judgment action. Thus, paragraph (*l*)(9)(B) serves one purpose and one purpose only: to provide the RPS with an exclusive remedy for a "[s]ubsequent failure to act by the subsection (k) applicant" that has chosen to participate in the patent-exchange provisions initiated with paragraph (*l*)(2)(A) disclosure.

Amgen argues that Apotex's interpretation of paragraph (*l*)(9)(B) is "triply wrong" because that paragraph, *first*, is not a remedy (because it merely lifts a bar on declaratory judgment actions); *second*, is not the exclusive remedy; and, *third*, does not prevent an injunction to require compliance with paragraph (*l*)(8)(A). Red Br. at 30. Amgen is incorrect on all counts.

First, paragraph (*l*)(9)(B) is a remedial provision because it permits a declaratory judgment action, which is a remedy. Amgen argued unsuccessfully in the *Sandoz* case that paragraph (*l*)(9)(C) was not a remedy, *see Sandoz*, 794 F.3d at 1355, yet this Court held that "when a subsection (k) applicant fails the disclosure requirement, 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e) expressly *provide the only remedies* as those being based on a claim of patent infringement." *Id.* at 1357 (emphasis added). So, too, here, paragraph (*l*)(9)(B) expressly provides the only remedy for a decision not to provide notice of commercial marketing as being based on a declaratory judgment action.

Second, Amgen argues that paragraph (*l*)(9)(B) is not the exclusive remedy, but no other provision of the BPCIA provides any other remedy. Amgen's argument that other, extra-statutory remedies are available simply assumes its conclusion—that an injunction to require compliance with paragraph (*l*)(8)(A) must be available in all cases. Yet, as discussed above, Amgen's premise that notice of commercial marketing is always required cannot be reconciled with the

provision in paragraph (*l*)(9)(B) spelling out the consequences when the applicant elects not to give notice.

Third, Amgen claims that paragraph (*l*)(9)(B) cannot preclude an injunction because this Court issued just such an injunction in *Sandoz*. As discussed below, however, the Sandoz court held that paragraph (*l*)(9)(B) *did not apply* to Sandoz. *Id.* at 1359. That is precisely why an injunction was available there but not here.

B. Apotex's Reading of the Statute Is Fully Consistent with *Amgen v. Sandoz*

This Court's *Amgen v. Sandoz* opinion involved a situation in which the applicant did *not* provide the disclosures under paragraph (*l*)(2)(A). The Court decided that the paragraph (*l*)(2)(A) disclosures are not mandatory, and its reasons for doing so are instructive for the present case. There, as here, Amgen argued that "shall" is always mandatory, but this Court rejected that argument. *Id.* at 1359. Although paragraph (*l*)(2)(A) states that the applicant "shall provide" a copy of its abbreviated Biologics License Application ("aBLA") and other information to the RPS, this Court determined that "the 'shall' provision in paragraph (*l*)(2)(A) cannot be read in isolation." *Id.* at 1355. Because other provisions in the statute—specifically, paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)—set forth the consequences of a decision not to provide the paragraph (*l*)(2)(A) disclosure, "'shall' in paragraph (*l*)(2)(A) does not mean 'must.' And the BPCIA has no other provision that grants a procedural right to compel compliance with the disclosure

requirement of paragraph (*l*)(2)(A)." *Id.* at 1355-56. The Court noted that "mandating compliance with paragraph (*l*)(2)(A) in all circumstances would render paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous, and statutes are to be interpreted if possible to avoid rendering any provision superfluous." *Id.* at 1356.

That same logic applies to this case: although Amgen argues at length that the "shall" in paragraph (*l*)(8)(A) means "must," that provision cannot be read in isolation. Because another part of the statute—namely, paragraph (*l*)(9)(B)—sets forth the consequences of a decision not to provide the paragraph (*l*)(8)(A) notice after an applicant has made the paragraph (*l*)(2)(A) disclosures, "shall" in paragraph (*l*)(8)(A) does not mean "must." And no other BPCIA provision grants a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(8)(A). Mandating compliance with paragraph (*l*)(8)(A) in all circumstances would, as noted above, render paragraph (*l*)(9)(B) superfluous.

When this Court in *Sandoz* turned to the question whether paragraph (*l*)(8)(A) is mandatory, it did so in the context of a case where the applicant had *not* made the paragraph (*l*)(2)(A) disclosures. This Court's *Sandoz* opinion left no doubt that the Court was considering "the consequence in this case"—*i.e.*, a case in which no paragraph (*l*)(2)(A) disclosures had been made—of its interpretation of

paragraph (*l*)(8)(A). *See id.* at 1358. The Court first recapitulated its reasoning regarding whether paragraph (*l)*(2)(A) was mandatory:

> As we have noted with respect to paragraph (*l*)(2)(A), however the BPCIA explicitly contemplates that a subsection (k) application might fail to comply with the requirement of paragraph (*l*)(2)(A) and further specifies the consequence for such failure in 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii). Because of those explicit statutory provisions, and to avoid construing the statute so as to render them superfluous, we have interpreted the BPCIA as allowing noncompliance with paragraph (*l*)(2)(A), subject to the consequence specified in those other provisions.

*Id.*at 1359.

Then the Court stated that, "with respect to paragraph (*l*)(8)(A), we do not find any provision in the BPCIA that contemplates, or specifies the consequence for, noncompliance with paragraph (*l*)(8)(A) *here*" – *i.e.*, on the facts of the case before it, where the applicant had not disclosed the information called for in paragraph (*l*)(2)(A). *Id.* (emphasis added). Precisely because Sandoz had elected *not* to make the paragraph (*l*)(2)(A) information disclosures, this Court held that paragraph (*l*)(9)(B) *did not apply*: "While it is true that paragraph (*l*)(9)(B) specifies the consequences for a subsequent failure to comply with paragraph (*l*)(8)(A) *after the applicant has complied* with paragraph (*l*)(2)(A), it does not apply in this case, where Sandoz did not comply with paragraph (*l*)(2)(A) to begin with." *Id.* (emphasis in original). Importantly, in this passage, this Court recognized that there could be situations where, like Apotex here, a biosimilar

applicant does not provide the notice of commercial marketing under paragraph (*l*)(8)(A) after it has participated in the disclosure requirements of paragraph (*l*)(2)(A).

The Court went on to comment that the remedy prescribed in paragraph (*l*)(9)(B) is not even possible unless the applicant has disclosed the information called for by paragraph (*l*)(2)(A):

> Indeed, the consequence specified in paragraph (*l*)(9)(B) is a declaratory judgment action brought by the RPS based on "any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7)." 42 U.S.C. § 262(*l*)(9)(B). Here, however, because Sandoz did not provide the required information to Amgen under paragraph (*l*)(2)(A), Amgen was unable to compile a patent list as described in paragraph (*l*)(3)(A) or paragraph (*l*)(7).

Id. Next, the Court observed that "nothing in subsection (*l*) excuses the applicant from its obligation to give notice of commercial marketing to the RPS *after it has chosen not to comply with paragraph (l)(2)(A)*." *Id.* at 1360 (emphasis added). At every turn, then, the Court limited its analysis to the facts then before it, where no paragraph (*l*)(2)(A) disclosures had been given. The Court's conclusion made this limitation explicit: "We therefore conclude that, *where, as here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline*, the requirement of paragraph (*l*)(8)(A) is mandatory." *Id.* (emphasis added).

In the present case, different facts compel a different result. Unlike Sandoz, Apotex here *did* provide the paragraph (*l*)(2)(A) information disclosures. Therefore, paragraph (*l*)(9)(B) *does* specify the consequence for a failure to comply with paragraph (*l*)(8)(A). Accordingly, the notice requirement of paragraph (*l*)(8)(A) should be construed as optional for Apotex for the same reason that the information disclosure requirement of paragraph (*l*)(2)(A) was construed as optional for Sandoz: Other provisions in the statute expressly anticipate that some applicants will elect not to provide the specified information and spell out the consequences of that decision; those provisions would be rendered superfluous if compliance were mandatory in every case.

C. Amgen's Reading of *Sandoz* Is Untenable

Amgen first excerpts and then overreads a passage from the Court's *Sandoz* opinion in which the Court first poses the question "whether the 'shall' provision in paragraph (*l*)(8)(A) is mandatory" and then answers: "We conclude that it is." *Id.* at 1359; *see* Red Br. at 5, 22, 27, 37, 39. Just like the "shall" in paragraph (*l*)(8)(A), which Amgen attempts to read in isolation and out of context, Amgen reads this passage in isolation and argues that it "is not limited to certain circumstances or certain Applicants; it is an unqualified assertion that paragraph (*l*)(8)(A) is mandatory." Red Br. at 5. Amgen even goes so far as to argue that, in the quoted sentence, this Court in *Sandoz* already decided the question presented in

the present case. *Id.* at 31. But Amgen ignores that this Court's whole discussion in *Sandoz* took place in the context of an applicant who had not made the information disclosures called for in paragraph (*l*)(2)(A), and that, as noted above, this Court repeatedly and explicitly qualified its holding to apply only to such facts. Nor can Amgen's suggestion that this Court has already decided the present question be squared with the reasoning of *Sandoz* itself, which, as explained above, rests critically on the premise that, in that case, paragraph (*l*)(9)(B) did not apply because Sandoz had not provided the information disclosures of paragraph (*l*)(2)(A). *See*, *e.g.*, *Sandoz*, 794 F.3d at 1360 ("We therefore conclude that, where, as here, a subsection (k) applicant completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline, the requirement of paragraph (*l*)(2)(A) is mandatory.").[1]

Amgen argues that this Court in *Sandoz* held that paragraph (*l*)(8)(A) is a "standalone" provision that is not conditioned on compliance or noncompliance with paragraph (*l*)(2)(A). *See* Red Br. at 37-39. But the word "standalone" is too thin a reed to bear the weight of Amgen's argument that paragraph (*l*)(8)(A) is

[1] Amgen oddly argues that because Judge Newman was part of the majority holding that notice of commercial marketing under paragraph (*l*)(8)(A) was mandatory in *Sandoz*, her separate opinion concurring in part and dissenting in part somehow broadens the majority holding. *See* Red Br. at 42. Apotex respectfully acknowledges the separate opinions authored by Judges Newman and Chen in *Sandoz* and, unless otherwise noted, bases its arguments herein on its reading of the controlling opinion of the Court authored by Judge Lourie.

mandatory for all applicants in all cases. In the context of *Sandoz*, the Court described paragraph (*l*)(8)(A) as a standalone provision in the sense that, "[u]nlike the actions described in paragraphs (*l*)(3) through (*l*)(7)," paragraph (*l*)(8) continues to apply to applicants who elect not to make the information disclosures of paragraph (*l*)(2)(A). *Sandoz*, 794 F.3d at 1360; *cf. id.* at 1371 (Chen, J., dissenting in part) ("[I]n my view, the better reading of (*l*)(8) is that it does not apply, just as (*l*)(3)–(*l*)(7) do not apply, when the (k) applicant fails to comply with (*l*)(2)."). The passage in question, and Judge Chen's response to it in dissent, make plain that the question before the Court was whether paragraph (*l*)(8)(A) continues to apply when the applicant elects not to provide the information disclosures of paragraph (*l*)(2)(A). The very next sentence of the Court's opinion emphasizes that point: "Moreover, nothing in subsection (*l*) excuses the applicant from its obligation to give notice of commercial marketing to the RPS *after it has chosen not to comply with paragraph (*l*)(2)(A)*." *Id.* at 1360 (emphasis added). This Court neither stated nor implied that a "standalone" notice provision is one that must be complied with mandatorily in every case, even when, as here, the statute prescribes the consequences of choosing not to provide the notice.

Amgen attempts to counter the Court's reasoning in *Sandoz* that paragraph (*l*)(9)(C) provides a remedy if a biosimilar applicant does not comply with the information disclosure requirement of paragraph (*l*)(2)(A) by pointing out that the

Court's opinion also referred to 35 U.S.C. §§ 271(e)(2)(C)(ii) and (e)(4). *See* Red Br. at 44-45. Those references to Title 35, however, do not detract from the Court's holding that paragraph (*l*)(9)(C) provides a remedy if a biosimilar applicant does not comply with the patent-dispute resolution procedures. *See Sandoz*, 794 at 1356 ("Notably, **both *42 U.S.C. § 262(l)(9)(C)*** and *35 U.S.C. § 271(e)(2)(C)(ii)* are premised on a claim of patent infringement, ...") (emphasis added); *see also id.* at 1357 (". . . we ultimately conclude that when a subsection (k) applicant fails the disclosure requirement, ***42 U.S.C. § 262(l)(9)(C)*** and 35 U.S.C. § 271(e) expressly provide the only **remedies** as those being based on a claim of patent infringement.") (emphases added).

Under the same logic applied by this Court in *Sandoz*, which found paragraph (*l*)(9)(C) to be a non-superfluous remedy provision that specifies the consequence if a biosimilar applicant like Sandoz chooses not to provide disclosures under paragraph (*l*)(2)(A), this Court should find paragraph (*l*)(9)(B) to be a non-superfluous remedy provision too. The paragraph (*l*)(9)(B) provision clearly specifies the consequence if a biosimilar applicant like Apotex—which does provide the paragraph (*l*)(2)(A) disclosures—does not then provide the paragraph (*l*)(8)(A) notice of commercial marketing.

Ultimately, in light of *Sandoz*, Amgen's position that it has the right to compel every applicant to give notice of commercial marketing under paragraph

(*l*)(8)(A) in every case cannot be reconciled with the provision in paragraph (*l*)(9)(B) that specifies the consequences in the event that the applicant chooses not to give the notice.

II. APOTEX'S INTERPRETATION COMPORTS WITH THE BPCIA'S EXCLUSIVITY PROVISION, THAT A SPONSOR RECEIVES ONLY 12 YEARS OF MARKET EXCLUSIVITY, NOT 12 ½ YEARS

Apotex's interpretation of paragraph (*l*)(8)(A) honors the balance that Congress struck between the rights of sponsors, biosimilar applicants, and the public in promoting innovation and increasing competition through easier, speedier access to biosimilar products. As detailed in Apotex's opening brief, the 12-year market exclusivity period provided by the BPCIA was a result of lengthy negotiation and determined to be commensurate in duration and scope to patent protection typically afforded to innovative drugs. *See* Apotex's Opening Br. at 30.

The district court's and Amgen's interpretation of paragraph (*l*)(8)(A), however, always leads to the same result: an applicant cannot market its biosimilar product until at least 12 ½ years after approval of the RPS's product. No matter whether the applicant submits its aBLA to the U.S. Food and Drug Administration ("FDA") 8 years, 10 years, 14 years, or 16 years after the RPS's product was approved by FDA, the result is the same under the district court's and Amgen's interpretation. Namely, the applicant will not be able to market its biosimilar product until after the RPS's 12-year market exclusivity provided by the BPCIA

has run and the additional 6 months provided by the district court's and Amgen's interpretation of paragraph (*l*)(8)(A). That result is contrary to the BPCIA's explicit 12-year, not 12 ½-year, market exclusivity.

Amgen argues that the last half-year of the 12 ½-year period is not truly an exclusivity period because another biosimilar applicant could be on the market. *See* Red Br. at 54-55. But that analysis is incorrect. No matter which biosimilar applicant is attempting to market its product, whether the first applicant or a subsequent applicant, the result is always the same: Under the district court's and Amgen's interpretation, all biosimilar applicants will first have to wait out the 12-year market exclusivity, and then wait out the additional 6 months exclusivity provided by paragraph (*l*)(8)(A).

Far from denying that the effect of its argument is to impose an extra six months of market exclusion, Amgen embraces the point. Indeed, Amgen goes so far as to state that this Court in *Sandoz* "recognized that Amgen would get in that case (and would get here) 180 days of 'market exclusion.' But it held that this consequence of the BPCIA is simply how the law works." *Id.* at 55. If that were correct, then this Court would presumably have said words to the effect that all future applicants should expect to wait an extra 180 days before launching their products. In fact, this Court said just the opposite: "That extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity

period for other products." *Sandoz*, 794 F.3d at 1358. Certainly, nothing in this Court's opinion indicates that it was prejudging the question whether applicants like Apotex, who disclose information pursuant to paragraph (*l*)(2)(A), must inevitably wait an extra 180 days before launching their products.

In sum, the effect of the district court's and Amgen's interpretation of the statute is to extend the statutory monopoly by six months, thus granting a windfall to reference product sponsors at the expense of patients who would benefit from more affordable biosimilar products. That result is counter to Congress's intent.

III. THE DISTRICT COURT'S AND AMGEN'S REASONING IS NOT IN HARMONY WITH THE PURPOSE OF THE BPCIA AND WOULD PRODUCE CONSEQUENCES NOT INTENDED BY CONGRESS

A. Requiring a Notice of Commercial Marketing is Not in Harmony with the Purpose of the Statute

The district court's and Amgen's reasoning that a compulsory notice of commercial marketing under paragraph (*l*)(8)(A) suddenly gives the RPS (Amgen) the right to file a preliminary injunction is premised on a fundamental misinterpretation of the rights a notice of commercial marketing provides. *See* Red Br. at 51. To be clear, a notice of commercial marketing under paragraph (*l*)(8)(A) gives the RPS a right to seek a preliminary injunction only on patents that were on its paragraph (*l*)(3)(A) list but that are not a part of the paragraph (*l*)(6) litigation. *See* Paragraph (*l*)(8)(B). Indeed, once the RPS has sued the biosimilar applicant in a paragraph (*l*)(6) litigation, as Amgen has done in this case, the RPS

instantaneously has the right to seek preliminary injunctive relief on the patents asserted in that litigation. Amgen presented, but has not actively pursued, a request for both preliminary and permanent injunctive relief based on the patents it asserted in its Complaint in this case, which is a paragraph (*l*)(6) litigation. *See* Appx56.

Amgen is fond of quoting a line from the Court's opinion in *Sandoz* in which the Court describes the purpose of notice of commercial marketing under paragraph (*l*)(8)(A) as "to allow the RPS a period of time to assess and act upon its patent rights." Red Br. at 17, 39, 41, 50. Amgen, however, does not need an additional 180 days to assess and act upon its patent rights because it has *already* sued Apotex on all of the patents on its paragraph (*l*)(3)(A) list; there is nothing else left to assess or to assert. There are no additional patents left on Amgen's paragraph (*l*)(3)(A) list that are not already a part of the pending paragraph (*l*)(6) litigation. Thus, nothing about a notice of commercial marketing alters Amgen's rights for seeking injunctive relief on the patents from its paragraph (*l*)(3)(A) list, because those patents are already in the pending litigation.

As detailed in Apotex's opening brief, because Apotex chose to participate in the disclosure requirements of paragraph (*l*)(2)(A), Amgen has now had over a year to review Apotex's aBLA and manufacturing information. Apotex's Opening Br. at 29. Amgen has therefore had more than ample time to identify all of the

patents that it believed could be reasonably asserted against Apotex based on Apotex's aBLA and manufacturing information. Thus, where, as here, the biosimilar applicant has followed the patent-dispute resolution procedures of the BPCIA, there can be no statutory purpose served by delaying the launch of a biosimilar product by another 180 days just so the sponsor has additional time to evaluate information that has already been in its possession since the time the aBLA was first accepted at the FDA. If Amgen thinks it can obtain an injunction based on the merits of its patent infringement case, it has long been free to ask for one.

Tellingly, however, instead of actively pursuing an injunction based on Apotex's infringement of the patents in suit, Amgen instead asked for and received an injunction on the purely procedural ground that Apotex has not yet given effective notice of commercial marketing under paragraph (*l*)(8)(A). Amgen did so even though the commercial marketing notice period cannot possibly bring to light any additional information about the product or the patents that Amgen does not already have. The injunction that Amgen obtained does nothing to further the purposes of the statute; it is an undisguised ploy to get an extra six months of undeserved monopoly profits based on a crabbed reading of the statute that ignores the teachings of *Sandoz*. In its brief, Amgen effectively admits that the waiting period serves no legitimate purpose in this case, but it offers the formalistic

argument that "Apotex cannot avoid the requirement of a statute by the specifics of this particular case." Red Br. at 54. This case provides an example, however, of why Amgen's proposed reading of the statute is unreasonable and unjust. This Court should reject Amgen's plea for an undeserved windfall of six months of monopoly profits.

B. Amgen's Reasoning Regarding Newly Issued or Licensed Patents Results from a Misunderstanding of the Statute

Amgen argues that a compulsory notice of commercial marketing would allow Amgen to assess and seek a preliminary injunction on any newly issued or licensed patents. *See* Red Br. at 52-53. This argument is premised on a misunderstanding of the interplay between paragraphs (*l*)(7), (*l*)(8)(A), (*l*)(9)(A) and (*l*)(9)(B). The mechanism for identifying newly issued or licensed patents is outlined in paragraph (*l*)(7), not paragraph (*l*)(8)(A). Under paragraph (*l*)(7), the RPS has 30 days from issuance or licensure of a patent to add the patent to its paragraph (*l*)(3)(A) list. Thus, an RPS's assessment of whether a newly issued or licensed patent is relevant is not premised on the notice of commercial marketing.

Further, in order to seek preliminary injunctive relief, an RPS must first include any newly issued or licensed patent in a litigation. This is where paragraphs (*l*)(9)(A) and (*l*)(9)(B) come in to play.[2] If the biosimilar applicant

[2] As Amgen acknowledges, it is unclear from the statute whether a newly issued or licensed patent can be added to an (*l*)(6) litigation after a RPS has placed

provides a notice of commercial marketing under paragraph (*l*)(8)(A), then an RPS (Amgen) may seek a declaratory judgment on any newly issued or licensed patents under paragraph (*l*)(9)(A). If a biosimilar applicant fails to provide a notice of commercial marketing under paragraph (*l*)(8)(A), then an RPS (Amgen) may seek a declaratory judgment on any newly issued or licensed patents under paragraph (*l*)(9)(B).

C. The District Court's and Amgen's Interpretation that Paragraph (*l*)(9)(B) is Not an Exclusive Remedy Disregards Congress's Intent

Whereas the district court interprets paragraph (*l*)(9)(B) as a nonexclusive remedy, Amgen characterizes paragraph (*l*)(9)(B) as not a remedial provision at all, much less an exclusive remedy. *See* Red Br. at 44. Either way, the BPCIA provides no remedy other than the one provided in paragraph (*l*)(9)(B) in the event that an applicant decides not to give the notice of commercial marketing called for in paragraph (*l*)(8)(A).

The district court's and Amgen's creation of an entirely new remedy that Congress did not provide in the BPCIA runs contrary to the well-settled doctrine, long recognized by the Supreme Court, that when Congress creates a new right in a statute and expressly provides the remedy for violation of that right, then the aggrieved party's relief is limited to that statutory remedy. *See*, *e.g.*, *Bruce's*

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the patent on its (*l*)(3)(A) list. Regardless, as explained above, paragraphs (*l*)(9)(A) and (*l*)(9)(B) provide a mechanism for placing these newly issued or licensed patents into litigation, *viz.*, through a declaratory judgment action.

Juices v. Am. Can Co., 330 U.S. 743, 755 (1947) ("'[W]here a statute . . . gives a new right and declares the remedy, . . . the remedy can be only that which the statute prescribes.'" (quoting *D.R. Wilder Mfg. Co. v. Corn Prods. Refining Co.*, 236 U.S. 165, 174-75 (1915); *Connolly v. Union Sewer Pipe Co.*, 184 U.S. 540 (1902))). The BPCIA provides one, and only one, remedy for situations where, as here, a biosimilar applicant has chosen to participate in the disclosures under paragraph (*l*)(2)(A) but then made a reasoned decision to refrain from giving notice of commercial marketing under paragraph (*l*)(8)(A), cognizant that such decision is governed by the consequences specified in paragraph (*l*)(9)(B). Courts should not craft new remedies when Congress has already exercised its power on the subject.

Amgen's assertion that paragraph (*l*)(9)(B) cannot be an exclusive remedy because it does not apply in all circumstances is again based on a misunderstanding of paragraph (*l*)(9)(B). *See* Red Br. at 46. Paragraph (*l*)(9)(B) applies only after a biosimilar applicant chooses to participate in the disclosure requirements of paragraph (*l*)(2)(A). Thus, it follows that if a biosimilar applicant chooses to participate in the disclosure requirements of paragraph (*l*)(2)(A) but thereafter refrains from participating in a "subsequent act," paragraph (*l*)(9)(B) always applies. Said differently, if a biosimilar applicant chooses to participate in the disclosure requirements of paragraph (*l*)(2)(A) but thereafter chooses to refrain from providing a notice of commercial marketing (one of the "subsequent acts"),

then the one and only remedy for the RPS is to file a declaratory judgment action under paragraph (*l*)(9)(B).

This Court should honor the plain text of the statute, its own prior logic in *Sandoz*, and the policies underlying the BPCIA and hold that, for parties that have complied with the information-exchange obligations of paragraphs *(l*)(2)-(*l*)(5), the notice of commercial marketing under paragraph (*l*)(8) is not mandatory.

CONCLUSION

This Court should reverse the district court's grant of a preliminary injunction and remand the case for further proceedings based on the correct interpretation of the BPCIA.

Dated: February 12, 2016

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32(A)(7)

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(b). This brief contains approximately 5729 words, excluding the part of the brief exempted by Fed. R. App. P. 32(a)(7)(b)(iii) and Fed. Cir. R. 32(b).

The 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 this brief has been prepared in a proportionally-spaced typeface using Microsoft Word 2013 in 14-point Times New Roman type.

February 12, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of February, 2016 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 Court's CM/ECF system.

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