UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY,	:	
Plaintiffs,	:	Civil Action No. 1:15-cv-10698-MLW
v.	:	
CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC.,	:	
Defendants.	:	

DEFENDANTS' SUPPLEMENTAL BRIEF ADDRESSING THE FEDERAL CIRCUIT'S DECISION IN *AMGEN v. SANDOZ* AND ITS EFFECT ON THE PARTIES' CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT AND PLAINTIFFS' MOTION FOR A PRELIMINARY AND PERMANENT INJUNCTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

INTRODUCTION

Janssen seeks an injunction that would delay Celltrion and Hospira's biosimilar launch by 180 days—even if Janssen's patent rights do not support injunctive relief. The Federal Circuit's recent decision in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015) (pet'ns for *en banc* rehearing filed Aug. 20, 2015), forecloses such extraordinary relief.

The parties' dispute concerns paragraph (*l*)(8)(A) of the Biologics Price Competition and Innovation Act ("BPCIA"). That section addresses a notice of commercial marketing provided by a biosimilar applicant to the reference product sponsor ("RPS" or "sponsor") "not later than 180 days before the date of the first commercial marketing" of the biosimilar product. 42 U.S.C. § 262(*l*)(8)(A). As discussed previously, this notice provision serves a limited purpose—it merely kick-starts a potential second litigation phase over patents whose relevance the parties dispute. (Defs' Opp'n Br. (Dkt. No. 51) at 5, 9-10.)

According to count 2 of Janssen's complaint, however, this provision requires the Court to enter an automatic, bondless 180-day injunction—for no purpose other than to exclude competition for another six months, regardless of patent protection. To obtain that extraordinary remedy, however, Janssen has a heavy burden. It must show that: (1) this notice of commercial marketing may not be given until FDA approves (or licenses) the biosimilar product; (2) the notice is mandatory even where, as here, the biosimilar applicant timely produces its application ("aBLA") under the BPCIA; *and* (3) the Act grants Janssen a private right of action for an automatic 180-day injunction, without satisfying the traditional four-factor test for injunctive relief.

Janssen argues that "the Federal Circuit resolved [these] legal questions . . . in [its] favor." (Br. 1.) Not so. True, the majority in *Amgen* alleviated Janssen's first burden by holding that, where notice is required, a biosimilar "applicant may only give effective notice of commer-

cial marketing after the FDA has licensed its product." 794 F.3d at 1358. But the rest of the court's decision bars the relief Janssen requests here.

Indeed, Janssen breaks up the language of the most relevant part of the *Amgen* decision, mischaracterizing it to say that "the Federal Circuit 'conclude[d]' that 'paragraph (l)(8)(A) is mandatory.'" (Br. 5.) In fact, the court held that the notice of commercial marketing provision is mandatory *only* where the biosimilar applicant "completely fails" to participate in the statutory information-exchange process. *Amgen*, 794 F.3d at 1360. As the key passage states in full: "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).

Tellingly, not once in its 20-page supplemental brief does Janssen quote this passage—even though we have expressly relied on, and directed Janssen to, this "completely fails" language. (Diskant Decl., Ex. 1.). Instead, based on an incomplete reading of the *Amgen* decision, Janssen says this: "[T]he fact that a notice of commercial marketing was mandatory in *Amgen* hardly suggests that it is *not* mandatory here. *Defendants' situation does not differ from Sandoz's in any way that is material to the Federal Circuit's interpretation of the BPCIA*." (Br. 3 (emphasis added).) Janssen is mistaken.

Unlike Sandoz, Celltrion (the applicant here) timely produced its aBLA to Janssen, and thus did not "*completely fail*[] to provide its aBLA and the required manufacturing information to [Janssen] by the statutory deadline." *Amgen*, 794 F.3d at 1360 (emphasis added). This distinction is not only material, but critical. The Federal Circuit "interpreted the BPCIA as allowing noncompliance" with a statutory requirement when the statute "contemplates, or specifies the consequence for, noncompliance." *Id.* at 1359. The court then recognized that the BPCIA "spe-

cifies the consequence" for failing to provide the notice of commercial marketing in paragraph (*l*)(9)(B). *Id*. Under the court's analysis, therefore, when those statutory consequences are available, the notice of commercial marketing provision is optional.

The court further qualified this analysis, however, by explaining that the statutory consequences for failing to provide notice of commercial marketing are available *only* if "the applicant has complied with" the statutory deadline for producing the aBLA and related information. *Id.* Because Sandoz had not provided any such information by the deadline, the court found that the consequence for failing to provide a notice of commercial marketing in paragraph (*l*)(9)(B) "d[id] not apply." *Id.* The court thus concluded by holding the notice of commercial marketing "mandatory" as to Sandoz *solely* because it had "completely fail[ed] to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline." *Id*. at 1360.

In contrast to Sandoz, Celltrion did timely provide its aBLA. Thus, paragraph (*l*)(9)(B) of the BPCIA prescribes the sole "consequence" for any failure by Celltrion to provide a notice of commercial marketing. *Id.* at 1359. The court's analysis in *Amgen* leads to an inescapable conclusion: "the requirement of paragraph (*l*)(8)(A) is" *not* "mandatory" here. *Id*. at 1360. If Celltrion chooses not to provide a notice of commercial marketing, that is "a path expressly contemplated by the BPCIA" that does "not violate the BPCIA." *Id.* at 1357.

While Janssen calls the reading we have outlined "incoherent" (Br. 18), one of the panelists expressly read the decision the same way we do. As Judge Chen noted, without contradiction by the majority: "Notably, nothing in the majority opinion suggests that this automatic [180-day] injunction remedy would be available in cases where the applicant complied with (*l*)(2)(A) by providing its aBLA to the RPS, but later failed to provide notice under (*l*)(8)(A)." *Id.* at 1371 (Chen, J., dissenting-in-part). Again, the majority did not dispute this reading.

For this reason alone, the Court should enter judgment for Defendants on count 2 of Janssen's complaint. But even if Janssen could show the notice provision is mandatory here, it still could not satisfy its final burden for the requested injunction—establishing a statutory cause of action to obtain a 180-day injunction without satisfying the traditional four-factor test. Supreme Court precedent bars Janssen's requested relief, further confirming that Janssen's motion for an automatic injunction should be denied.

BACKGROUND

A. The *Amgen* decision

In *Amgen*, the biosimilar applicant (Sandoz) completely failed to timely produce its aBLA and manufacturing information pursuant to the BPCIA. *Amgen*, 794 F.3d at 1360. Sandoz took the position that the Act does not require such production. The Federal Circuit addressed this statutory question along with the notice of commercial marketing provision.

On July 7, 2014, the FDA accepted Sandoz's aBLA seeking approval to market a biosimilar of Amgen's Neupogen product. *Id*. at 1352. The next day Sandoz both notified Amgen that it had filed an aBLA referencing Neupogen and provided Amgen its notice of commercial marketing, informing Amgen that Sandoz intended to launch its biosimilar product as soon as it receives FDA approval. *Id.* at 1352-53.

Having quarreled with Amgen over the terms for confidential access to Sandoz's aBLA, Sandoz "opted not to provide … [its] biosimilar application within 20 days of the FDA's notification of acceptance." *Id.* at 1353. The 20-day period to initiate the BPCIA's information exchanges (sometimes referred to as the "patent dance") thus expired without Sandoz having "disclose[d] its aBLA or its product's manufacturing information to Amgen according to § 262(*l*)(2)(A)." *Id.* Amgen therefore sued, alleging (among other things) that Sandoz had "violated the BPCIA by failing to disclose the required information under § 262(*l*)(2)(A) and by

giving a premature, ineffective, notice of commercial marketing under § 262(*l*)(8)(A) before FDA approval of its biosimilar product." *Id.* The district court ruled for Sandoz on both issues. *Id.*

Amgen appealed, and sought an injunction pending appeal under the traditional four-factor test for such relief. *See* Motion for an Injunction Pending Appeal (Dkt. No. 55) and Order Granting Motion (Dkt. No. 105) in *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir.) (Hoang Exs. 7-8). The Federal Circuit granted the requested injunction. *Amgen*, 794 F.3d at 1362. Then, in a later split-decision on the merits, the court entered three holdings relevant to this case.

First, the court held that although the BPCIA says that the biosimilar applicant "shall provide" its application, this does not impose a mandatory requirement, because the BPCIA and Patent Act "expressly provide the only remedies as those being based on a claim of patent infringement." *Id*. at 1355, 1357. As the Federal Circuit explained, the BPCIA's "'shall' provision … cannot be read in isolation." *Id.* at 1355. The court noted that "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, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." *Id.* at 1356. "Moreover, 35 U.S.C. § 271(e)(4) provides 'the *only* remedies which may be granted by a court for an act of infringement described in paragraph (2).'" *Id.* Thus, when "the BPCIA explicitly contemplates that a subsection (k) applicant might fail" to take action required by the statute and "specifically sets forth the consequence for such failure," this indicates that "'shall' … does not mean 'must.'" *Id.* at 1355. Otherwise, "mandating compliance [with the "shall" provision] in all circumstances would render [the consequence provisions] superfluous, and statutes are to be interpreted if possible to avoid rendering any provision superfluous." *Id*. at 1356.

Second, the court "conclude[d] that, under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product." *Id.* at 1358. For this reason, the Federal Circuit found that Sandoz's notice of commercial marketing sent in July 2014—prior to FDA licensure—was legally ineffective.[1]

Third, and most pertinent here, the court held that the notice of commercial marketing provision is mandatory only when the applicant "completely fails" to participate in the statutory information-exchange procedures:

> 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. Sandoz therefore may not market Zarxio before 180 days from March 6, 2015, *i.e.*, September 2, 2015.

Id. at 1360 (emphasis added). The Federal Circuit reiterated that, where the BPCIA's provisions "explicitly contemplate[] that a [biosimilar] applicant might fail to comply … and further specifies the consequence for such failure," the BPCIA must be construed to allow for noncompliance to avoid rendering those provisions superfluous. *Id.* at 1359. It also found that "paragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with [the notice of commercial marketing provision] *after the applicant has complied* with paragraph (*l*)(2)(A)." *Id.* The court nonetheless held that paragraph (*l*)(9)(B) "does not apply in this case, where Sandoz did not comply with paragraph (*l*)(2)(A) to begin with." *Id.*

---

[1] Unless the ruling is overturned, as Defendants told Janssen, their notice of commercial marketing "was not effective under the majority's decision in *Amgen*." (Diskant Decl., Ex. 1.) But Defendants did not, as Janssen asserts, "concede that *Amgen* compels granting Plaintiffs' motion for summary judgment on the merits." (Br. 1.) Indeed, as discussed in this brief, Janssen still does not have a viable claim based on an alleged violation of paragraph (*l*)(8)(A), because Janssen has no "claim of 'injury' here." (Defs' Opp'n Br. (Dkt. No. 51) at 17-18.) That is, under *Amgen*, there is no statutory basis to compel Defendants to provide any notice of commercial marketing. Therefore, *Amgen* warrants granting partial summary judgment to Defendants on the merits of count 2 of the complaint.

Viewed collectively, these holdings establish that (1) where a notice of commercial marketing is required, it must await FDA licensure; but (2) such notice is not mandatory unless the applicant "completely fails" to participate in the BPCIA patent-exchange process. *Id.* at 1360. The court has apparently read the BPCIA to prevent a situation where the applicant does not disclose its application and launches upon FDA approval without any prior notice to the sponsor. *See id.* (noting that "paragraph (*l*)(8)(A) ... require[s] notice of commercial marketing be given to allow the [sponsor] a period of time to assess and act upon its patent rights"). That is, if the applicant "completely fails" to participate in the statutory patent process, that applicant must provide a notice of commercial marketing after FDA approval but 180 days before the product launch. But where the applicant does participate in the patent dance, the BPCIA expressly spells out—in paragraph (*l*)(9)(B)—the consequence for any noncompliance with the notice provision.

B. The statutory patent exchange in this litigation

Unlike in *Amgen*, Celltrion provided its aBLA to Janssen, and thus participated in the BPCIA patent process, within the 20-day statutory deadline. *See* 42 U.S.C. § 262(*l*)(2)(A) (saying the "applicant" "shall provide" the aBLA and other information "[n]ot later than 20 days after" FDA accepts the application). (*See* Defendants' Statement of Material Facts ("DSMF," Dkt. No. 52), ¶¶ 10-12.) Celltrion's production of its aBLA included information detailing the process used to manufacture Celltrion's proposed biosimilar product.[2]

[2] Janssen disputes that Celltrion provided all of the necessary manufacturing information. (Br. 16-17.) We disagree. But in any case, Janssen has never argued—nor could it—that Celltrion completely failed to provide its aBLA and manufacturing information. Indeed, as Defendants have explained in response to Janssen's motion to modify the stipulated protective order, Celltrion's aBLA includes detailed manufacturing information that Janssen intends to rely upon in its infringement case. (Defs' Opp'n to Motion to Modify the Stipulated Protective Order (Dkt. No. 73-1) at 4-5.)

In response, Janssen served its patent list pursuant to the process set out in the BPCIA, identifying six patents. (*Id.* ¶ 13.) Defendants provided their detailed statement and also agreed that each of the patents identified by Janssen would be the subject of an immediate patent infringement suit. (*Id.* ¶¶ 14-15.) At the same time, Defendants also served their notice of commercial marketing. (*Id.* ¶ 16.)

In response, Janssen (along with NYU) filed this action, asserting infringement of all six patents identified during the patent dance. (*Id.* ¶¶ 17-20.) Janssen also alleged, among other things, that Defendants violated paragraph (*l*)(8)(A) by serving an ineffective notice of commercial marketing and sought to enjoin Defendants' biosimilar launch "until at least 180 days after Defendants provide Janssen with proper notice." (*Id.* ¶ 18; Compl. at 31, 35.)

ARGUMENT

Under a straightforward reading of *Amgen*, the BPCIA's notice of commercial marketing provision "is mandatory" only if a biosimilar applicant "*completely fails* to provide its aBLA and the required manufacturing information to the RPS" within 20 days of FDA accepting the aBLA. 794 F.3d at 1360 (emphasis added). Because Sandoz failed to provide its aBLA to Amgen, the court there was not called upon to address the precise factual situation before the Court here—where Celltrion did provide such information. As shown below, however, the court's analysis as a whole permits only one conclusion: the BPCIA does not require Celltrion, which *did* timely produce its aBLA, to provide any notice of commercial marketing. *Amgen* thus forecloses Janssen's claim in count 2 of its complaint that Defendants violated the notice provision and Janssen's related request for an automatic, bondless injunction divorced from patent rights.

I. *Amgen* forecloses Janssen's claim for violating the notice of commercial marketing provision, which is not mandatory here.

A. Under *Amgen*, the notice is mandatory *only* where the applicant "completely fails to provide its aBLA and required manufacturing information."

Although the notice of commercial marketing provision says the "applicant shall provide notice," the court in *Amgen* properly held that the use of "shall" in the BPCIA "cannot be read in isolation"—and does not necessarily mean "must." 42 U.S.C. § 262(*l*)(8)(A); *Amgen*, 794 F.3d at 1355. In fact, as the Federal Circuit held, the statutory language saying the applicant "shall provide" its aBLA within a particular time period "does *not* mean 'must.'" *Id*. (emphasis added). The key inquiry is whether the statute also provides a remedy for statutory non-compliance. If so, when the applicant fails to comply with the statute, it does "not violate the BPCIA"—it simply triggers the available remedy. *Id.* at 1357.

The Federal Circuit's analysis in this regard applies equally to the notice of commercial marketing provision, which says the applicant "shall provide" such notice "not later than 180 days before" commercial marketing of the biosimilar. 42 U.S.C. § 262(*l*)(8)(A). The BPCIA provides an express remedy for violating this notice provision:

> 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 included in the list described in paragraph (3)(A), including as provided under paragraph (7).

Id. § 262(*l*)(9)(B) (emphasis added). Thus, if the applicant fails to provide a notice of commercial marketing, the sponsor (but not the applicant) may immediately file a declaratory judgment action and assert any "patents that the parties initially identified during [the BPCIA] information exchange but were not selected for the immediate infringement action, as well as any newly issued or licensed patents" (the "phase-two patents"). *Amgen*, 794 F.3d at 1352.

The court in *Amgen* addressed this issue and, in a sentence relied on heavily by Janssen, stated: "A question exists ... concerning whether the 'shall' provision in paragraph (*l*)(8)(A) is mandatory [in light of paragraph (*l*)(9)(B)]. We conclude that it is." *Id.* at 1359. But the court did not stop there. It expressly limited this conclusion to the facts before it—namely, where Sandoz "completely fail[ed] to provide its aBLA and the required manufacturing information to [Amgen] by the statutory deadline." *Id.* at 1360. And the court's reasoning made clear that it was drawing a sharp distinction between situations where the applicant provides its aBLA within the 20-day deadline and situations where it fails to do so. Indeed, Judge Chen's dissent read the majority's opinion to draw this distinction, and the majority did not dispute that reading. *Id.* at 1371 (Chen, J., dissenting-in-part) ("Notably, nothing in the majority opinion suggests that this automatic [180-day] injunction remedy would be available in cases where the applicant complied with (*l*)(2)(A) by providing its aBLA to the RPS, but later failed to provide notice under (*l*)(8)(A).").

Taken as a whole, therefore, the court's ruling confirms that the notice of commercial marketing provision is *not* mandatory where, as here, the applicant does timely provide its aBLA under the statute. As the court explained, "to avoid construing the statute so as to render [statutory provisions] 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. The court also found it "true that paragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with paragraph (*l*)(8)(A) *after the applicant has complied* with paragraph (*l*)(2)(A) [requiring production of the aBLA.]" *Id.* (emphasis in original).

Nevertheless, the court found that this statutory remedy "does not apply in this case, where Sandoz did not comply with paragraph (*l*)(2)(A) to begin with." *Id*. That is because the

court did "not find any provision in the BPCIA that contemplates, or specifies the consequence for, noncompliance with paragraph (*l*)(8)(A) *here*"—i.e., where Sandoz refused to participate in the BPCIA patent exchange and thus never "complied with paragraph (*l*)(2)(A)." *Id.* (emphasis added). In other words, the notice of commercial marketing provision is *not* mandatory—by virtue of the statutory consequence in paragraph (*l*)(9)(B)—unless the applicant "completely fails" to participate in the BPCIA patent process. *Id.* at 1360.

The court further explained that "[p]aragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*)." *Id.* at 1359. But this does not mean, as Janssen suggests, that the notice provision is mandatory in all BPCIA cases. Instead, as the context makes clear, the court merely emphasized that "nothing in subsection (*l*) excuses [Sandoz] from its obligation to give notice of commercial marketing to [Amgen] after [Sandoz] has chosen not to comply with paragraph (*l*)(2)(A)." *Id.* at 1360. That is, Sandoz could not avoid the notice of commercial marketing by refusing to participate in the "patent dance."

The court's analysis then closed with the conclusion most pertinent here—again, a conclusion that expressly limits the court's holding to the particular circumstances of that case:

> 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). Once again, one searches Janssen's 20-page brief in vain for even a single reference to the phrase "completely fails." Each time Janssen quotes part of the passage above, it omits that language. Yet the omitted language is devastating to Janssen's position.

Where, as here, the applicant participates in the BPCIA patent exchange by providing the sponsor immediate access to the application—and therefore does not "completely fail[]" to comply with paragraph (*l*)(2)(A)—the sponsor can exercise its patent rights well before FDA approval. To the extent patents are disputed, there will be at least a first litigation phase addressing

the key disputed patents and related claims for injunctive relief. And, under the analysis in *Amgen*, once the applicant notifies the sponsor of the aBLA and starts to participate in the patent-exchange process, the BPCIA—and in particular, i.e., paragraph (*l*)(9)(B)—provides the sole remedy for a failure to provide a notice of commercial marketing. The Act authorizes no other remedy, let alone an automatic 180-day injunction. *See id.* at 1356; *see also* 35 U.S.C. § 271(e)(4) (providing that the statutory remedies are "the *only* remedies which may be granted by a court for an [artificial] act of infringement" under the BPCIA) (emphasis added).

In sum, an applicant that participates in the patent process but fails to provide a notice of commercial marketing does "not violate the BPCIA"—it merely takes "a path expressly contemplated by the BPCIA." *Amgen*, 794 F.3d at 1357, 1360.

B. Defendants did not "completely fail" to provide Celltrion's aBLA and manufacturing information.

Celltrion complied with paragraph (*l*)(2)(A). In fact, Janssen has not alleged, and cannot allege, that Celltrion "completely fail[ed] to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline." *Id.* at 1360. On the contrary, Janssen expressly alleges that Celltrion "provide[d] Janssen with a copy of [its] aBLA (No. 125544) twenty days after the application was accepted for review by FDA." (Compl. ¶ 104; *see also* Br. 17 ("Defendants provided Plaintiffs a copy of their aBLA.").) Based on Celltrion's disclosure of information—including detailed manufacturing information within the aBLA—Janssen developed a list of asserted patents and ultimately brought this infringement suit.

Under *Amgen*, Celltrion's participation in the BPCIA patent exchange triggers the remedy provision in paragraph (*l*)(9)(B)—namely, "the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28" on any phase-two patents—should Defendants fail to provide effective notice of commercial marketing upon FDA

approval. Again, this situation is materially different from that presented in *Amgen*, where "Amgen was unable to compile a patent list as described in paragraph (*l*)(3)(A) or paragraph (*l*)(7)" because Amgen had not even seen Sandoz's application before bringing suit. 794 F.3d at 1359. Here, unlike in *Amgen*, the remedy in paragraph (*l*)(9)(B) governs and, therefore, the notice of commercial marketing provision is not mandatory.

Janssen argues that Celltrion did not comply with the paragraph (*l*)(2)(A) disclosure requirements because it did not produce third-party confidential data concerning manufacturing. (Br. 17.) But Celltrion had no statutory obligation to produce *third-party* data, as the BPCIA provides that confidential information to be disclosed under the BPCIA "is, and shall remain, the property of the subsection (k) applicant." *See* 42 U.S.C. § 262(*l*)(1)(E). Needless to say, third-party data are not "the property of the subsection (k) applicant." *Id.* Regardless, Janssen's argument ignores the unambiguous holding in *Amgen*—namely, that the notice provision is mandatory only where the applicant "completely fails" to provide *both* "its aBLA *and* the required manufacturing information to the RPS by the statutory deadline." *Amgen*, 794 F.3d at 1360 (emphasis added). Again, Janssen makes no effort to satisfy the court's actual holding.

C. This case illustrates why the notice of commercial marketing is not always mandatory, and not mandatory here.

The Federal Circuit's explanation that the notice of commercial marketing is not mandatory in cases such as this one makes perfect sense. The notice provision serves a limited purpose—it kick-starts any second litigation phase over patents whose relevance the parties dispute. Many (perhaps most) BPCIA lawsuits, including this one, will have only one litigation phase, because the parties will frequently agree that all patents should be litigated. The notice provision is relevant only in a subset of cases—cases where such an agreement cannot be reached—and there is no reason for such notice to be mandatory in all cases.

Here is how the statute works under *Amgen*: If the biosimilar applicant declines to timely produce its aBLA and manufacturing information under paragraph 262(*l*)(2)(A), the sponsor may bring an immediate declaratory judgment suit for infringement of *any* patent it considers relevant. *See* 42 U.S.C. § 262(*l*)(9)(C). But if the applicant timely provides its aBLA (as Celltrion did here), the sponsor prepares a list of patents that could support an infringement claim. *Id*. § 262(*l*)(3)(A)(i). The applicant then responds with its own list. *Id*. § 262(*l*)(3)(B). The parties thus try to agree on "which, if any, patents" will be litigated (*id.* § 262(*l*)(4)(A))—i.e., the "patent dance." Whether by agreement or statutory procedure, the parties produce a final list of patents that may give rise to "immediate" litigation. *Id.* § 262(*l*)(6)(A), (B).

The notice of commercial marketing determines when the parties may litigate any patents that did not make the final list, or were issued or licensed after the BPCIA patent process—i.e., the phase-two patents. Generally, when the parties have participated in the patent dance, neither the sponsor nor the applicant may sue on any of these phase-two patents "prior to the date [such] notice is received." *Id.* § 262(*l*)(9)(A). The notice thus lifts the bar on litigating phase-two patents. When provided, the notice triggers a 180-day period for the sponsor to "seek" (not automatically obtain) a preliminary injunction barring the launch of products that allegedly infringe those patents—i.e., the phase-two patents. *Id*. § 262(*l*)(8)(A), (B).

In *Amgen*, the Federal Circuit confirmed that the notice of commercial marketing concerns only phase-two patents—i.e., it "allows the [sponsor] a period of time to seek a preliminary injunction *based on patents that the parties initially identified during information exchange but were not selected for the immediate infringement action*, as well as any newly issued or licensed patents." 794 F.3d at 1352 (emphasis added). The court held that this 180-day period can begin

no earlier than FDA approval. *Id.* at 1358. But there is no reason to impose such a 180-day launch delay in all cases.

This case provides a perfect example for why the notice provision should not be deemed mandatory in all BPCIA cases. Here, Celltrion accepted Janssen's patent list and Janssen immediately sued on all listed patents. Thus, there are no "phase-two" patents to litigate. The notice of commercial marketing—which merely triggers litigation over those patents—serves no purpose here. The sponsor (Janssen) already is aware of the underlying application and already has asserted all patents it has identified as potentially relevant to Celltrion's application. This is part of the reason why the *Amgen* panel recognized that notice is not mandatory unless the applicant "completely fails to provide its aBLA and the required manufacturing information to the RPS by the statutory deadline." *Id.* at 1360. After all, why should Defendants be required to provide a notice that serves no statutory purpose—particularly if the effect of such unnecessary notice delays competition for 180 days, thus harming consumers who stand to benefit from a lower-priced biosimilar? Janssen has no persuasive answer.

According to Janssen, the purpose of the notice provision is to provide a post-approval, pre-launch "'statutory window' for assessing the need for a preliminary injunction based on a 'fully crystallized' product." (Br. 12.) But neither the statute nor the *Amgen* decision supports that view. The plain text of paragraph (*l*)(8)(B) says the notice of commercial marketing allows the sponsor to "seek a preliminary injunction" only with respect to those patents that, based on the patent-list exchanges, have been relegated to potential phase-two litigation. 42 U.S.C. § 262(*l*)(8)(B). And again, this is precisely how the Federal Circuit *majority*—not the dissent, as Janssen argues (Br. 11)—construed the statute. *See Amgen*, 794 F.3d at 1352 (explaining that the notice provision "allows the [sponsor] a period of time to seek a preliminary injunction *based*

on patents that the parties initially identified during information exchange but were not selected for the immediate infringement action, as well as any newly issued or licensed patents") (emphasis added). Particularly where no preliminary injunction on any phase-two patents is sought or justified—i.e., where no phase-two patents remain—the notice provision should not be construed to impose a mandatory statutory window.

In short, the notice of commercial marketing not only is optional here in light of *Amgen*, but would serve no purpose other than providing Janssen with a 180-day windfall monopoly at consumers' expense. And since Janssen has no legal basis to compel Defendants' compliance with the notice provision, Defendants are entitled to partial summary judgment on count 2 of the complaint.

D. Janssen cannot salvage Count 2 by arguing that the remedy in paragraph (*l*)(9)(B) is "meaningless."

Although its brief is not entirely clear on this point, Janssen appears to ask this Court to ignore the statutory remedy in paragraph (*l*)(9)(B) because it "is meaningless." (Br. 16.) Janssen is wrong. But if it believes the statutory remedy for failing to provide an effective notice of commercial marketing is "meaningless," its remedy lies with Congress—not this Court.

"When," as here, "a statute expressly provides remedies, courts must be extremely reluctant to expand its sweep by augmenting the list of prescribed anodynes ... [and] should ordinarily conclude that the legislature provided precisely the redress it considered appropriate." *Sterling Suffolk Racecourse Ltd. P'ship v. Burrillville Racing Ass'n, Inc.*, 989 F.2d 1266, 1270 (1st Cir. 1993). As the Supreme Court held in *Alexander v. Sandoval*, "[t]he express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others." 532 U.S. 275, 290 (2001). Likewise, the Federal Circuit has held that "when legislation expressly provides a particular remedy or remedies, courts should not expand the coverage of the statute to

subsume other remedies." *Consol. Edison Co. of N.Y. v. O'Leary*, 117 F.3d 538, 544 (Fed. Cir. 1997).

Amgen expressly stated that where, as here, the applicant does not "completely fail" to participate in the patent dance, "paragraph (*l*)(9)(B) specifies the consequence for a subsequent failure to comply with [the notice of commercial marketing provision]." 794 F.3d at 1359-60. Congress could have prescribed a different remedy, such as granting the sponsor an automatic injunction. But Congress prescribed no such remedy, even though it prescribed that remedy elsewhere in the BPCIA. *See* 42 U.S.C. § 262(*l*)(1)(H) (creating a presumption of "irreparable harm" for breaches of confidentiality). As the Supreme Court has emphasized, and as we have previously explained (Defs' Opp'n Br. (Dkt. No. 51) at 18-20), "[t]he courts should not create liability ... where Congress has elected not to." *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2118 (2014).

Nor is there any basis to Janssen's suggestion that the statutory remedy chosen by Congress is "meaningless." First, the BPCIA does not in any way deny Janssen any "right to seek a preliminary injunction." (Br. 15-16.) Janssen is free to seek a preliminary injunction now on any of the patents-in-suit. *See* 35 U.S.C. § 271(e)(2)(C). *Amgen* does not hold otherwise.

Second, even where the parties agree to divide the BPCIA litigation into two phases (unlike here), the point of the patent exchange is to identify the most relevant patents—including those most likely to support injunctive relief—to be litigated in phase one. Again, the sponsor can seek a preliminary injunction as to any of those phase-one patents well before FDA approval, notwithstanding any notice of commercial marketing (or lack thereof).

Third, the statutory remedy is still appropriate even in the hypothetical and highly speculative situation where (1) an applicant participates in the patent exchange, (2) the litigation is di-

vided into two phases, (3) the sponsor believes a phase-two patent could support a preliminary injunction, but (4) the applicant intends to launch without first providing notice of commercial marketing. In that instance, the sponsor may seek to stop that launch by bringing an immediate declaratory judgment action, including a request for a temporary restraining order or preliminary injunction, on any phase-two patents. 42 U.S.C. § 262(*l*)(9)(B). The key issue for the courts would be whether the sponsor's *patent rights* justify depriving consumers of a lower-priced biosimilar. Janssen has yet to make any such showing here.

II. Even if the Court were to find the notice provision mandatory here, imposing an automatic injunction would violate *eBay*.

Even if this Court were to find that the BPCIA's notice provision is mandatory here, it would still be inappropriate to enter the automatic 180-day injunction that Janssen seeks. Nothing in the BPCIA alters the longstanding rule that "whether to grant or deny injunctive relief rests within the equitable discretion of the district courts," or that "such discretion must be exercised consistent with traditional principles of equity." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006). Moreover, the Supreme Court "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows" a statutory violation. *Id*. at 392-93.

Although the merits panel in *Amgen* did not expressly apply the four-factor *eBay* test, the opinion relied on its earlier decision granting an injunction pending appeal, which was based on that test. *Supra* at Hoang Exs. 7, 8. As the panel explained, shortly after noticing its appeal, "Amgen ... filed an emergency motion in [the Federal Circuit] for an injunction pending appeal" based on the four-factor test, and the court "granted the motion." *Amgen*, 794 F.3d at 1362. The panel went on to state that, "[i]n light of what we have decided concerning … the contested provisions of the BPCIA, we accordingly order that the injunction pending appeal be extended

through September 2, 2015." *Id.* In other words, the panel found that it need not *re-apply* the four-factor test to justify extending a previously issued injunction. (*See* Amgen Resp. to Pet. for Rehearing *En Banc* (Dkt. No. 155) in *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir.) at 4 ("There is no *eBay* issue, because the initial injunction pending appeal was granted based on the traditional, four-factor equitable test of likelihood of success, irreparable harm, balance of the equities, and consideration of the public interest.") (Hoang Ex. 9.).

Thus, *Amgen* does not impose an automatic 180-day injunction if an applicant fails to provide a mandatory notice of commercial marketing. Instead, under *eBay*, the four-factor injunction test still must be satisfied. And it cannot be satisfied here. (*See* Defs' Opp'n Br. (Dkt. No. 51) at 16-26.)

Indeed, a rule providing for an automatic injunction would be especially hard to reconcile with the BPCIA. As other provisions of that Act confirm, Congress knew how to create a presumption favoring injunctions. In paragraph (*l*)(1)(H), Congress stated that the unwarranted disclosure of any confidential information "shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy." 42 U.S.C. § 262(*l*)(1)(H). Further, Congress amended the Patent Act to state, in circumstances not at issue here, that "the court shall order a permanent injunction … ." 35 U.S.C. § 271(e)(4)(D).

Congress included no language authorizing injunctions in paragraph 8. And "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (quotation omitted). Thus, there is no basis to provide Janssen an automatic 180-day injunction, thus ex-

tending sponsors' 12-year marketing exclusivity to 12.5 years. *See* 42 U.S.C. § 262(k)(7)(A) (providing 12 years, not 12.5 years, of marketing exclusivity).[3]

CONCLUSION

Defendants respectfully request that this Court deny Plaintiffs' motion for partial summary judgment and a preliminary and permanent injunction on count 2 of the complaint and grant Defendants partial summary judgment as to that count.

Dated: September 16, 2015

Respectfully submitted,

By: */s/ Andrea L. Martin*
Dennis J. Kelly (BBO # 266340)
dkelly@burnslev.com
Andrea L. Martin (BBO #666117)
amartin@burnslev.com
BURNS & LEVINSON LLP
125 Summer Street
Boston, MA 02110-1624
Telephone: 617-345-3000
Facsimile: 617-345-3299

Of Counsel:

WINSTON & STRAWN LLP

Charles B. Klein, admitted *pro hac vice*
Steffen N. Johnson, admitted *pro hac vice*
1700 K Street NW
Washington, DC 20006
Phone: (202) 282-5000
cklein@winston.com
sjohnson@winston.com

[3] Janssen cannot credibly argue that it "needs" a 180-day injunction "to assess its rights and decide whether to seek a preliminary injunction" based on "at least one of Janssen's manufacturing patents." (Br. 18.) As discussed in a different brief, Janssen has conceded that the manufacturing product at issue does not literally satisfy many patent claim elements and thus, for this reason alone, could not credibly support the extraordinary remedy of an injunction. (Defs' Opp'n to Motion to Modify the Stipulated Protective Order (Dkt. No. 73-1) at 18-19, 20 n.5.)

Samuel S. Park, admitted *pro hac vice*
Dan H. Hoang, admitted *pro hac vice*
35 West Wacker Drive
Chicago, Illinois 60601-9703
Phone: (312) 558-5600
spark@winston.com
dhoang@winston.com

Attorneys for Defendants Celltrion Healthcare Co., Celltrion, Inc., and Hospira, Inc.

CERTIFICATE OF SERVICE

I, Andrea L. Martin, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on September 16, 2015.

/s/Andrea L. Martin, Esq.
Andrea L. Martin, Esq.

4837-2969-4760.1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and NEW YORK UNIVERSITY, Plaintiffs, v. CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC., Defendants.	:	Civil Action No. 1:15-cv-10698-MLW

DECLARATION OF DAN H. HOANG IN SUPPORT OF DEFENDANTS' SUPPLEMENTAL BRIEF ADDRESSING THE FEDERAL CIRCUIT'S DECISION IN *AMGEN V. SANDOZ* AND ITS EFFECT ON THE PARTIES' CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT AND PLAINTIFFS' MOTION FOR A PRELIMINARY AND PERMANENT INJUNCTION

I, Dan H. Hoang, declare as follows:

1. I am an attorney at the Chicago office of Winston & Strawn LLP representing Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc. in the above-captioned case. I am a member in good standing of the Bar of the State of Illinois and have been admitted to practice *pro hac vice* by Order of this Court dated April 8, 2015, Dkt. 33.

2. I offer this declaration in support of Defendants' supplemental brief addressing the Federal Circuit's decision in *Amgen v. Sandoz* and its effect on the parties' cross-motions for partial summary judgment and Plaintiffs' motion for a preliminary and permanent injunction, filed concurrently herewith.

3. Attached hereto as **Exhibit 7** is a true and correct copy of the Non-Confidential Emergency Motion of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited for an Injunction Pending Appeal Pursuant to Fed. R. App. P. 8(a) in *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir.) (Dkt. No. 55), filed on April 17, 2015.

4. Attached hereto as **Exhibit 8** is a true and correct copy of the Order on the Emergency Motion of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited for an Injunction Pending Appeal Pursuant to Fed. R. App. P. 8(a) in *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir.) (Dkt. No. 105), filed on May 5, 2015.

5. Attached hereto as **Exhibit 9** is a true and correct copy of the Response of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited to Defendant-Appellee Sandoz Inc.'s Petition for Rehearing En Banc in *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir.) (Dkt. No. 155), filed on September 8, 2015.

Executed in Chicago, Illinois on September 16, 2015.

/s/ Dan H. Hoang

Dan H. Hoang
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601-9703
Phone: (312) 558-5600
dhoang@winston.com

CERTIFICATE OF SERVICE

I, Andrea L. Martin, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on September 16, 2015.

/s/Andrea L. Martin, Esq.
Andrea L. Martin, Esq.

4820-2182-6344.1

EXHIBIT 7

Appeal No. 2015-1499

United States Court of Appeals

for the

Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

– v. –

SANDOZ INC.,

Defendant-Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA IN CASE NO. 3:14-CV-04741-RS, JUDGE RICHARD SEEBORG

NON-CONFIDENTIAL EMERGENCY MOTION OF PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING LIMITED FOR AN INJUNCTION PENDING APPEAL PURSUANT TO FED. R. APP. P. 8(a)

NICHOLAS GROOMBRIDGE
ERIC ALAN STONE
JENNIFER H. WU
JENNIFER GORDON
PETER SANDEL
MICHAEL T. WU
ARIELLE K. LINSEY
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, New York 10019
(212) 373-3000

VERNON M. WINTERS
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, California 94104
(415) 772-1200

WENDY A. WHITEFORD
LOIS M. KWASIGROCH
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, California 91320
(805) 447-1000

Attorneys for Plaintiffs-Appellants

April 17, 2015

CERTIFICATE OF INTEREST

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

   AMGEN INC. and AMGEN MANUFACTURING LTD.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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

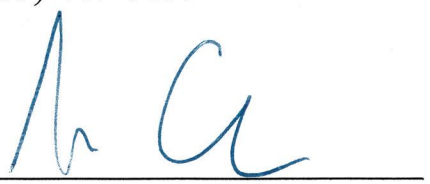
   AMGEN INC.

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

Nicholas Groombridge
Eric Alan Stone
Jennifer H. Wu
Jennifer Gordon
Peter Sandel
Michael T. Wu
Arielle K. Linsey
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Vernon M. Winters
Alexander D. Baxter
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, CA 94104
(415) 772-1200

Wendy A. Whiteford
Lois M. Kwasigroch
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000



Nicholas Groombridge

TABLE OF CONTENTS

Page

STATEMENT OF OPPOSITION

Pursuant to Federal Circuit Rule 27(a)(5), counsel for Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Ltd. (together, "Amgen") informed counsel for Defendant-Appellee Sandoz Inc. ("Sandoz") of Amgen's intent to file this motion and sought Sandoz's position. Sandoz indicated that it opposes the motion. The parties have agreed to an expedited schedule for this motion, and Amgen is concurrently submitting an unopposed motion reflecting that schedule.

CONFIDENTIAL MATERIAL OMITTED

Pursuant to Federal Circuit Rule 27(m), Amgen has prepared a public version of this motion that omits certain confidential information. Specifically, the material omitted on pages 5 and 17 contains references to Sandoz's confidential information regarding Sandoz's pricing strategy and marketing and sales strategy. The omitted information was designated confidential by Sandoz during discovery under the terms of the Protective Order entered by the district court.

In addition, Amgen has attached public versions of exhibits in support of this motion that omit certain confidential information. Specifically, the material omitted in the exhibits contains Amgen's confidential information regarding market analysis, and sales, pricing, and revenue forecasts, and Sandoz's confidential information regarding pricing strategy and marketing and sales strategy. The omitted information was designated confidential by Amgen and Sandoz under the terms of the Protective Order entered by the district court.

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES (CONTINUED)

Page(s)

STATUTES

OTHER AUTHORITIES

PRELIMINARY STATEMENT

Sandoz is poised to begin commercial marketing of the first FDA-approved biosimilar, which is a copy of Amgen's innovative NEUPOGEN® biological product. Sandoz has agreed to stay off the market only until May 11, 2015 absent judicial intervention. The commercial marketing and sale of Sandoz's biosimilar product ZARXIO® will be in direct competition with Amgen's NEUPOGEN® and will fundamentally and permanently alter the market, causing irreparable harm to Amgen if this Court ultimately reverses the district court's decision. Accordingly, Amgen respectfully requests that this Court enter an injunction during the appeal, before the status quo is irrevocably changed. Amgen's requested injunction will be short: the merits briefing will be completed by April 28, 2015, and the parties have requested oral argument in June 2015. (Dkt. No. 19.)

This case presents issues of first impression regarding the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, 124 Stat. 119, 804 (2010). Before 2010, FDA approved biological products under only 42 U.S.C. § 262(a), which typically requires three phases of clinical trials to prove safety, purity, and potency. *Compare* 42 U.S.C. § 262 (2007), *with* 42 U.S.C. § 262 (2010). The BPCIA created a new, abbreviated regulatory pathway, codified in 42 U.S.C. § 262(k), for approval of a biological product as "biosimilar to" a "reference product" that FDA had previously licensed under 42 U.S.C. § 262(a).

Amgen's position is that when a "subsection (k) applicant" (or "Applicant") uses this new regulatory pathway it commits to complying with the mandatory provisions of the BPCIA; it may not follow the provisions it likes and opt out of those it does not. Sandoz's position, which the district court adopted, is that an Applicant may opt in or out of statutory provisions depending on whether it wishes to take advantage of their benefits.

Sandoz submitted an application for ZARXIO® under the abbreviated pathway, referencing Amgen's license for its NEUPOGEN® (filgrastim) product. Ex. 1 at A0005. This lawsuit arose because Sandoz submitted a biologics license application (a "BLA") and pursued FDA approval and threatened to launch its product without complying with the pre- and post-FDA-approval BPCIA provisions that protect the rights of Amgen (the "reference product sponsor" or "RPS"), including the statute's disclosure and patent-dispute process. As the district court stated, "there is no dispute that Sandoz did not engage in 42 U.S.C. § 262's disclosure and dispute resolution process." Ex. 1 at A0002.

Amgen has demonstrated a substantial case on the merits that the statute creates mandatory obligations by the Applicant to the RPS, that Sandoz failed to satisfy those obligations, and that the statute does not foreclose the courts' remedial powers to compel compliance with those obligations. The district court made three fundamental errors of law:

First, § 262(*l*)(2)(A) requires an Applicant to provide a copy of its BLA and information about the manufacture of its proposed biosimilar product to the RPS within 20 days of FDA accepting the BLA for review. Sandoz did not do this. Ex. 1 at A0002. Nevertheless, the district court held that Sandoz was within its rights to elect not to do so. Ex. 1 at A0018. This was error.

Second, § 262(*l*)(8)(A) requires the Applicant to provide at least 180 days' notice before the first commercial marketing of "the biological product licensed under subsection (k)." Sandoz provided this notice when FDA accepted its BLA for review, rather than after FDA approval when its product became "licensed under subsection (k)." Ex. 4 at A0065-66, 71; Ex. 9 at A1472. Nevertheless, the district court held that Sandoz's notice was timely. Ex. 1 at A0014. This too was error.

Third, the district court held that even if Sandoz was required to provide its BLA and manufacturing information and even if Sandoz gave untimely notice of commercial marketing, the BPCIA does not permit the courts to compel compliance with the statute, instead limiting any remedy to the RPS bringing a declaratory judgment of infringement, validity, or enforceability of a patent. Ex. 1 at A0014 n.8, 18. This again was error because the BPCIA forecloses no applicable remedies, and district courts should have a broad range of tools available where an Applicant violates the statute.

From its erroneous reading of the BPCIA, the district court further erred in denying Amgen's motion for a preliminary injunction to compel Sandoz to comply with the terms of the BPCIA as properly construed. After entry of judgment, the district court also declined to enter an injunction pending appeal under Fed. R. Civ. P. 62(c) (Ex. 15 at A2078-80), reasoning that "any detriment Amgen endures due to market entry of Sandoz's biosimilar product is only undue if Sandoz has infringed an Amgen patent." Ex. 15 at A2080.

Accordingly, Amgen respectfully requests an injunction pursuant to Fed. R. App. P. 8(a) preventing Sandoz from marketing, selling, offering for sale, or importing into the United States its FDA-approved ZARXIO® biosimilar product until this Court resolves the appeal.

FACTUAL BACKGROUND

A. Amgen's Innovator Product, NEUPOGEN®, and Sandoz's Biosimilar Filgrastim Product, ZARXIO®

In 1991, Amgen obtained regulatory approval for NEUPOGEN® under the traditional biological product regulatory pathway, 42 U.S.C. § 262(a), including demonstrating to the FDA that NEUPOGEN® "is safe, pure, and potent." Ex. 1 at A0005; 42 U.S.C. § 262(a)(2)(C)(i)(I). The active ingredient in NEUPOGEN® is filgrastim, which stimulates the production of white blood cells known as neutrophils. Ex. 4 at A0058.

In 2014, Sandoz filed a BLA under the BPCIA's abbreviated pathway of 42 U.S.C. § 262(k) for approval of its biosimilar filgrastim product, designating Amgen's NEUPOGEN® as the reference product. Ex. 1 at A0005; Ex. 9 at A1472. FDA notified Sandoz that it had accepted its BLA for review on July 7, 2014. Ex. 1 at A0005. FDA approved Sandoz's BLA on March 6, 2015. Ex. 12 at A1775. Sandoz will market its filgrastim product under the name ZARXIO®, *id.*, in direct competition with NEUPOGEN® for each of NEUPOGEN®'s FDA-approved indications. Ex. 12 at A1783. It is undisputed that Sandoz intends to price ZARXIO® [redacted]

B. Sandoz's Refusal to Comply with the BPCIA

Despite availing itself of the benefits of the abbreviated pathway conferred by referencing Amgen's biological license, Sandoz refused to follow the statutory requirements of the BPCIA that protect Amgen's patent rights. Had Sandoz complied with those provisions, Amgen would have been able to identify those patents for which Amgen believes a patent infringement claim could reasonably be asserted, leading to additional exchanges that would have resulted in either a negotiated resolution of the patent disputes or an informed patent-infringement lawsuit under § 262(*l*)(6). Ex. 4 at A0071-72. Without Sandoz's disclosure,

Amgen was materially prejudiced because it was denied the time and information to detect Sandoz's patent infringement and commence an action under the BPCIA before FDA licensure of the biosimilar product. Ex. 4 at A0071-73.

In addition, Sandoz refused to provide Amgen with 180 days' notice of commercial marketing after FDA licensure of the biosimilar product, as required by § 262(*l*)(8)(A). Instead, Sandoz attempted to provide notice prematurely at the same time that FDA accepted its BLA for review, eight months prior to FDA licensure. Ex. 9 at A1472; Ex. 4 at A0071; Ex. 12 at A1774. Had Sandoz given notice after FDA licensure (and not before), Amgen could have had notice of the product that was actually licensed (rather than the biological product that is the subject of the FDA application), and thus used the notice period to commence an orderly preliminary injunction process as contemplated by § 262(*l*)(8)(B).

PROCEDURAL HISTORY

On March 19, 2015, the district court: (1) granted Sandoz's motion for judgment that its reading of the BPCIA is correct, (2) rejected Amgen's motion for judgment on the pleadings that Sandoz's refusal to comply with the BPCIA was a violation of California Unfair Competition Law (Cal. Bus. & Prof. Code § 17200 et seq.) (the "UCL"), and (3) denied Amgen's motion for a preliminary injunction that Sandoz comply with the BPCIA's requirements as Amgen understands them. Ex. 1 at A0001-19.

On March 25, 2015, the district court entered final judgment under Rule 54(b) as to the BPCIA claims. Ex. 2 at A0020-23. Amgen timely appealed both the judgment and the district court's denial of Amgen's motion for a preliminary injunction. Ex. 3 at A0024-26. The district court denied Amgen's motion for an injunction pending appeal on April 15, 2015, asserting that Amgen would suffer undue harm only if "Sandoz has infringed an Amgen patent." Ex. 15 at A2080.

ARGUMENT

This Court grants injunctions pending appeal based on a determination of "(1) whether the movant has made a strong showing of likelihood of success on the merits; (2) whether the movant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *See AstraZeneca LP v. Breath Ltd.*, No. 15-1335, Dkt. No. 46, at 2 (Fed. Cir. Mar. 12, 2015) (nonprecedential).

I. Amgen is Likely to Succeed on the Merits

This Court reviews the district court's interpretation of the BPCIA de novo, and reviews the denial of Amgen's preliminary injunction motion for abuse of discretion, reversing if "'the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings.'" *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*,

686 F.3d 1348, 1352 (Fed. Cir. 2012) (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997)). Here, Amgen is likely to succeed on the merits of this appeal because the district court erred in its interpretation of the BPCIA. Specifically, the district court's reading of the BPCIA converts a statute designed to balance the interests of the Applicant and the RPS into one that vitiates the benefits afforded to the RPS. That was not what Congress intended. Congress enacted the BPCIA as part of the Affordable Care Act, because it was "the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804.

On the one hand, Applicants and the public benefited from the new pathway because it diminished innovators' previous enjoyment of permanent and exclusive rights to their clinical trial data and FDA license. In the BPCIA, Congress advanced the public's interest in price competition by, for example: allowing an Applicant to "reference" the RPS's license and thereby rely on the safety and efficacy of the RPS product, rather than generating its own clinical trial data; limiting an innovator's data exclusivity to twelve years; and allowing the Applicant to enter a market with established demand for the reference product.

On the other hand, Congress protected the RPS and the public's interest in innovation and preserving patents, in part by creating an exchange, negotiation, and patent resolution process in 42 U.S.C. § 262(*l*), "Patents." That subsection

requires the Applicant to provide the RPS with the BLA for the proposed biosimilar and manufacturing information, and requires the parties to identify patents and exchange detailed infringement, validity, and enforceability contentions. The statute then creates a new "Immediate patent infringement action" under 42 U.S.C. § 262(*l*)(6). Subsection 262(*l*)(8) also preserves the status quo for an 180-day period between FDA licensure of a biosimilar product and its first commercial availability so that the RPS may seek injunctive relief on patents that are not listed for the § 262(*l*)(6) litigation.

A. Amgen Will Show that The District Court Erred in Holding that the Requirement of 42 U.S.C. § 262(*l*)(2)(A) Is Not Mandatory

Subsection 262(*l*) creates a detailed, elaborate procedure for patent-dispute resolution. It begins within twenty days of the Applicant being notified by FDA that its BLA has been accepted for review; the Applicant "shall provide" to the RPS a copy of the BLA "and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A).

Following receipt of the BLA and manufacturing information, § 262(*l*)(3) requires the RPS (and the Applicant if it chooses) to provide a list of patents for which "a claim of patent infringement could reasonably be asserted," and to discuss whether the parties are willing to license those patents and whether the Applicant will remain off the market until their expiry. For any other listed

patents—*i.e.*, those for which there is an active dispute—the parties must provide detailed statements describing, claim-by-claim, the factual and legal basis for their contentions regarding infringement, validity, and enforceability. *See* 42 U.S.C. § 262(*l*)(3)(B), (C). Sections (*l*)(4) and (*l*)(5) then require that the Applicant and RPS jointly determine which of the patents identified in the (*l*)(3) exchange shall be the subject of an "[i]mmediate patent infringement action" that the reference product sponsor "shall bring." *Id.* § 262(*l*)(6).

Despite the entire process hinging on the provision of a copy of the BLA and manufacturing information under 42 U.S.C. § 262(*l*)(2)(A), the district court held that an Applicant may "elect" not to provide that information. Ex. 1 at A0009, 18. The court held that an Applicants and RPS "may participate" in the provisions of § 262(*l*), but that "these procedures are 'required'" only "where the parties elect to take advantage of their benefits." Ex. 1 at A0001, 9. The district court erred.

The statute explicitly says that the provision of the BLA and manufacturing information is mandatory. Subsection 262(*l*)(2)(A) says the Applicant "shall provide" its BLA and manufacturing information "[n]ot later than 20 days" after receiving notice that FDA has accepted its BLA for review. "Shall" is generally mandatory language. *See*, *e.g.*, *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661-62 (2007); *Lopez v. Davis*, 531 U.S. 230, 241 (2001); *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998).

This is particularly true where, as here, "shall" is juxtaposed with "may." *See, e.g., Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 346 (2005). Under § 262(*l*)(2), the Applicant "shall" provide its BLA and manufacturing information, and "may" provide anything else that the RPS requests. Furthermore, the BPCIA refers to the provision of the Applicant's BLA and manufacturing information as "required" in four separate places. *See* 42 U.S.C. § 262(*l*)(1)(B)(i), (9)(A), (9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). In two, it refers to non-provision of the information as "fail[ure]." *See* 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

The district court based its decision in part on its belief that permitting Sandoz "not to comply" with § 262(*l*) "operates to promote expedient resolution of patent disputes." Ex. 1 at A0011. This turns the statute on its head. In crafting the BPCIA, Congress created a new, "[i]mmediate" patent infringement lawsuit under § 262(*l*)(6). Many other provisions, affecting the rights of the Applicant, the RPS, the public, and even other biosimilar applicants targeting the same reference product, are affected by whether and when a § 262(*l*)(6) lawsuit is filed. *See*, *e.g.*, 42 U.S.C. § 262(k)(6); 35 U.S.C. § 271(e)(4)(D), (e)(6). By allowing the Applicant to prevent a § 262(*l*)(6) lawsuit from ever being filed, the district court toppled the statutory balance in favor of the Applicant and allowed Applicants to game the system.

B. Amgen Will Show that the District Court Erred in Holding that an Applicant May Give Notice of Commercial Marketing Before FDA Licensure of its Biosimilar Product

Subsection 262(*l*) recognizes that there may be patents that read on the biosimilar product and the methods of its manufacture that were initially included in the parties' lists under § 262(*l*)(3) but were not listed for inclusion in the § 262(*l*)(6) lawsuit, as well as "[n]ewly issued or licensed patents" that become part of the RPS's § 262(*l*)(3)(A) list by virtue of § 262(*l*)(7). The BPCIA provides for certain litigation over these patents once FDA licenses the biosimilar product and the Applicant gives the at-least-180-days' notice provided for by § 262(*l*)(8)(A). Provision of that notice triggers preliminary injunction practice for these patents under § 262(*l*)(8)(B), and declaratory judgment actions under § 262(*l*)(9)(A).

Nevertheless, the district court held it was "not wrongful for Sandoz to give Amgen its 180 days' notice prior to first commercial marketing pursuant to subparagraph (*l*)(8)(A) in July 2014, in advance of receiving FDA approval." Ex. 1 at A0014. The district court erred.

Subsection 262(*l*)(8)(A) requires the Applicant to give notice of commercial marketing of "the biological product licensed under subsection (k)" (emphasis added). Everywhere else § 262(*l*) refers to the product, it uses a variant of "the biological product that is the subject of" the BLA. *See* 42 U.S.C. § 262(i)(2),

(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(3)(B)(ii)(I), (*l*)(3)(C), (*l*)(7)(B). The distinction is significant: An Applicant may not give 180 days' notice until the product that was "the subject of the application" becomes a "biological product licensed"—*i.e.*, until after FDA licensure. Everywhere else that 42 U.S.C. § 262 uses the term "product licensed," it refers to a product that FDA has already licensed. *See* 42 U.S.C. § 262(d)(1), (i)(4), (k)(5).

The district court's interpretation—that an Applicant may give notice when FDA accepts its BLA for review—frustrates the purpose of the notice, which is to allow the RPS time to seek a preliminary injunction on the patents not listed for inclusion in the § 262(*l*)(6) lawsuit. *See* 42 U.S.C. § 262(*l*)(8)(B). Providing notice when the BLA is accepted for review means that those patents have not even been identified. That would render the notice meaningless to the RPS.

C. Amgen Will Show that the District Court Erred in Holding that Subsection 262(*l*)(9) Provides the Exclusive Remedy for Failure to Comply with Subsection 262(*l*)(2)(A) or 262(*l*)(8)(A)

The district court held that even if an Applicant is required by § 262(*l*)(2)(A) to provide its BLA and manufacturing information, and even if the Applicant provides untimely notice or no notice at all under § 262(*l*)(8)(A), the only remedy available to the RPS is to bring a declaratory judgment on a patent under § 262(*l*)(9). Ex. 1 at A0014 n. 8, 18. That declaratory judgment is the "exclusive consequence[]," and the RPS may not "obtain injunctive relief, restitution, or

damages against the applicant." Ex. 1 at A0018. That was error.

A declaratory judgment action under § 262(*l*)(9) is not a remedy for a violation of the BPCIA itself, nor is it exclusive, and district courts should have a broad range of tools available, under federal and state law, to compel an Applicant to comply with the BPCIA.

First, § 262(*l*)(9)(C) is limited to a declaration of infringement, validity, or enforceability of "any patent that claims the biological product or a use of the biological product." It is not a remedy for failure to provide the BLA and manufacturing information required by § 262(*l*)(2)(A), without which the RPS often will be unable to tell what patents are infringed, and thus on which patents the RPS should commence litigation. Indeed, § 262(*l*)(9)(C) does not mention patents covering the Applicant's manufacturing processes. It cannot be the case that the consequence for Applicant's failure to provide manufacturing information is that the Applicant may avoid litigation on manufacturing patents altogether.

Second, a declaratory judgment action provides no remedy to the RPS where the Applicant provides untimely notice, or no notice, of commercial marketing under § 262(*l*)(8)(A). If the Applicant starts marketing its product without notice, the RPS can seek emergency relief for infringement under 35 U.S.C. § 271. A declaratory judgment action affords the RPS no way to remedy the harm of a lack of timely notice.

Third, nothing in the BPCIA says declaratory judgment actions under § 262(*l*)(9) are exclusive. If the Applicant fails to take a required action, the RPS "may" bring a declaratory judgment action. The statute does not say "shall bring" a declaratory judgment action, or "may bring only" such an action. When Congress intends remedies to be exclusive, it says so explicitly, as it did in 35 U.S.C. § 271(e)(4), which sets forth "the only remedies which may be granted" for infringement under § 271(e)(2) other than attorneys' fees, and in 35 U.S.C. § 271(e)(6)(B), which provides "the sole and exclusive remedy that may be granted" where an RPS does not timely commence the § 262(*l*)(6) lawsuit on a listed patent. There is no parallel in the statute here. Nothing in the BPCIA says that declaratory judgment actions under § 262(*l*)(9) are an exclusive remedy, or prohibits any remedy where an Applicant fails to comply with the statute's terms.

Further, should this Court hold that Sandoz's conduct is unlawful, then Amgen has stated claims under California state law—for UCL and conversion—that can be based on violations of or the misuse of privileges and rights under federal law. *See*, *e.g.*, *G.S. Rasmussen & Assocs., Inc. v. Kalitta Flying Serv., Inc.*, 958 F.2d 896 (9th Cir. 1992); *Citizens for a Better Env't-California v. Union Oil of California*, 996 F. Supp. 934 (N.D. Cal. 1997); *Farmers Ins. Exch. v. Superior Court*, 2 Cal. 4th 377, 383 (1992).

II. Amgen Faces Irreparable Harm Without an Injunction Pending Appeal

Without an injunction, Sandoz has agreed to stay off the market until only May 11, 2015. Should Sandoz launch in violation of the BPCIA (under Amgen's reading), Amgen will be irreparably harmed. Accordingly, Amgen seeks an injunction during the pendency of this appeal.

In denying Amgen's motion for a preliminary injunction, and then again in denying Amgen's motion for an injunction pending appeal, the district court found Amgen had not shown irreparable harm because Amgen's evidence was "highly speculative" and "based on the as-yet unproven premise that Sandoz has infringed a valid patent belonging to Amgen." Ex. 1 at A0018; *accord* Ex. 15 at A2080. That is error. The harm to Amgen does not depend on Sandoz having infringed an Amgen patent; it arises independently from Sandoz's product entering the market on a biological license it secured without having complied with the *Patents* provision of the BPCIA. By refusing to provide the required BLA and manufacturing information, Sandoz materially prejudiced Amgen, depriving it of the time, which can be up to 230 days, and information needed to detect Sandoz's infringement and commence an § 262(*l*)(6) action under the BPCIA before FDA licensure. By refusing to provide 180-day advance notice after FDA licensure, Sandoz denied Amgen the statutory period to seek a preliminary injunction on the licensed product. And the harms wrought by Sandoz's unlawful competition are

not speculative, they are immediate and real. Amgen will face price erosion, patent uncertainty, and harm to its goodwill and customer relationships, which cannot be remediated by a later-issued injunction or by money damages.

Price Erosion: It is undisputed that Sandoz intends to price ZARXIO® [redacted] Ex. 8 at A1444; Ex. 10 at A1682-83. [redacted] Ex. 6 at A0477-79; Ex. 14 at A1997; Ex. 7 at A0516-17. Amgen will therefore suffer irreparable harm in the form of price erosion immediately upon ZARXIO®'s launch at a lower price. This is particularly true because Sandoz [redacted] and the market for filgrastim is price-sensitive with no unmet clinical need. *See* Ex. 13 at A1992-93; Ex. 6 at A0477-78. Thus, sales of ZARXIO® will come at the expense of NEUPOGEN®, to which it is biosimilar. Ex. 6 at A0477.

If ZARXIO®'s launch is not enjoined but this Court ultimately reverses the district court decision, Amgen would find itself in a situation where "it would be very difficult if not impossible for Amgen to simply raise its prices back to what they were before ZARXIO[®] competition." Ex. 6 at A0479. Under Medicare reimbursement rules, any rapid attempt to rehabilitate NEUPOGEN®'s price would

put customers underwater—that is, their acquisition cost would exceed their reimbursement—and a slower attempt to rehabilitate NEUPOGEN®'s price would mean the effects of price erosion would persist longer. Ex. 6 at A0479-80. Thus, Amgen will face irreparable price erosion, just as any innovative pharmaceutical would suffer harm from unlawful generic competition. *See, e.g.*, *Abbott Labs. v. Sandoz Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008) (generic Biaxin®); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1381 (Fed. Cir. 2006) (generic Plavix®).

"Patent Uncertainty": Amgen has approximately 400 patents directed to methods of manufacturing recombinant proteins. Ex. 5 at A0473. By refusing to provide its BLA and manufacturing information as required by § 262(*l*)(2)(A), Sandoz made it impossible for Amgen to determine which of these patents read on the manufacture of Sandoz's biological product. Allowing an Applicant to market its product without complying with the BPCIA procedures that protect the RPS's patent rights undermines the value of those patents irreparably, as well as investors' confidence that such patents will protect the risk-based investments made by innovative companies like Amgen. This is the unrebutted testimony of Amgen's economic expert. *See* Ex. 7 at A0518-19, 21; Ex. 11 at A1749-50.

Loss of Goodwill and Harm to Customer Relationships: If Sandoz launches ZARXIO® before this appeal is resolved, and Amgen lowers its price for NEUPOGEN®, Amgen will suffer irreparable harm to its reputation, consumer

relationships, and goodwill if it later prevails on this appeal and tries to restore pricing. Ex. 7 at A0522-23; Ex. 6 at A0479-80. As noted above, Medicare reimbursement rules would prevent rapid price rehabilitation without significantly harming Amgen's consumer relationships, and a slower rehabilitation would entail lingering price erosion effects. Ex. 6 at A0479-80. Restoring prices, as well as market reaction to Sandoz's entry and withdrawal, could thus unfairly harm Amgen for enforcing its legal rights

III. The Equities and Public Interest Favor Granting an Injunction Pending Appeal

The district court did not reach the balance-of-equities and public-interest prongs of the injunction test. Both favor an injunction here.

Balance of Equities: Postponing the launch of ZARXIO® until after this appeal is unlikely to have a significant impact upon Sandoz. Whatever sales it loses in the brief period of an injunction are not irreparable and can be compensable by money ameliorated by a bond. Amgen will be prepared to address the calculation of a bond if the Court enters an injunction.

While Sandoz also says it could face competition from another, not-yet-approved biosimilar filgrastim product, if true that is a harm of Sandoz's own making: had it timely complied with the BPCIA, it would have been many months ahead of the next biosimilar competitor(s).

Amgen, on the other hand, faces immediate and irreversible price erosion, devastating injury to its consumer relationships and goodwill, and diminution in the value of its patents. As such, the balance of hardships clearly favors a short injunction of Sandoz's sales of ZARXIO® pending this appeal.

Public Interest: The public interest also favors an injunction. There is a strong public interest in encouraging investment in drug development, and the fact that a generic (or, here, a biosimilar) may sell at a lower price does not override that important concern. *See Sanofi-Synthelabo*, 470 F.3d at 1383-84. Moreover, if Sandoz is permitted to launch ZARXIO® before the resolution of this appeal, other biosimilar applicants will be incentivized to behave as Sandoz has done, breaching the clear terms of the BPCIA that serve to preserve incentives to innovators to engage in biologics discovery.

CONCLUSION

For the foregoing reasons, Amgen respectfully requests that the Court enjoin Sandoz from marketing, selling, offering for sale, or importing into the United States its ZARXIO® biosimilar product during this appeal.

Dated: April 17, 2015

Respectfully submitted,

Nicholas Groombridge
Eric Alan Stone
Jennifer H. Wu
Jennifer Gordon
Peter Sandel
Michael T. Wu
Arielle K. Linsey
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Vernon M. Winters
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, CA 94104
(415) 772-1200

Wendy A. Whiteford
Lois M. Kwasigroch
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

Attorneys for Plaintiffs-Appellants

Appeal No. 2015-1499

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC., AMGEN MANUFACTURING LTD.,

Plaintiffs-Appellants,

v.

SANDOZ INC.,

Defendant-Appellee.

Appeal from the United States District Court for the Northern District of California in Case No. 3:14-CV-04741, Judge Richard Seeborg

---

ORDER

Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Ltd. (together, "Amgen") move for an injunction pending appeal pursuant to Fed. R. App. P. 8(a).

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The motion is granted.

(2) Sandoz and all those acting in concert with it or on its behalf, are enjoined from marketing, selling, offering for sale, or importing into the United States any biosimilar filgrastim product until such time that this Court decides Amgen's appeal.

_____, 2015 _____

EXHIBIT 8

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,
Plaintiffs-Appellants

v.

SANDOZ INC.,
Defendant-Appellee

2015-1499

Appeal from the United States District Court for the Northern District of California in No. 3:14-cv-04741-RS, Judge Richard Seeborg.

ON MOTION

PER CURIAM.

O R D E R

Amgen Inc. et al. move for an injunction "preventing Sandoz [Inc.] from marketing, selling, offering for sale, or importing into the United States its FDA-approved ZARXIO® biosimilar product until this Court resolves the appeal." Sandoz opposes.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The motion is granted, effective immediately.

(2) The parties are directed to respond concerning what amount of a bond, if any, should be posted for each day that the injunction is in place. Sandoz shall file, within seven days of this order, a document not to exceed 10 pages explaining what amount of bond should be posted. Amgen shall file, within seven days of Sandoz's filing, a response not to exceed 10 pages. The bond amount will be determined by subsequent order of the court.

FOR THE COURT

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

EXHIBIT 9

Appeal No. 2015-1499

United States Court of Appeals

for the

Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

– v. –

SANDOZ INC.,

Defendant-Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA IN CASE NO. 3:14-CV-04741-RS, JUDGE RICHARD SEEBORG

RESPONSE OF PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING LIMITED TO DEFENDANT-APPELLEE SANDOZ INC.'S PETITION FOR REHEARING EN BANC

NICHOLAS GROOMBRIDGE
ERIC ALAN STONE
JENNIFER H. WU
JENNIFER GORDON
PETER SANDEL
MICHAEL T. WU
ARIELLE K. LINSEY
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, New York 10019
(212) 373-3000

VERNON M. WINTERS
ALEXANDER D. BAXTER
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, California 94104
(415) 772-1200

WENDY A. WHITEFORD
LOIS M. KWASIGROCH
KIMBERLIN L. MORLEY
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, California 91320
(805) 447-1000

Attorneys for Plaintiffs-Appellants

CERTIFICATE OF INTEREST

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

   AMGEN INC. and AMGEN MANUFACTURING LTD.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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

   AMGEN INC.

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

Nicholas Groombridge
Eric Alan Stone
Jennifer H. Wu
Jennifer Gordon
Peter Sandel
Michael T. Wu
Arielle K. Linsey
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Vernon M. Winters
Alexander D. Baxter
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, CA 94104
(415) 772-1200

Wendy A. Whiteford
Lois M. Kwasigroch
Kimberlin L. Morley
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

/s/ Nicholas Groombridge
Nicholas Groombridge

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

INTRODUCTION

Sandoz asks the full Court to rehear (1) the Panel's unanimous decision that notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) is effective only if given after FDA approval of the biosimilar, not before; and (2) the propriety of the Panel's extending an existing injunction pending appeal through September 2, 2015, 180 days after Sandoz's March 6, 2015 notice of commercial marketing.

Amgen respectfully submits that en banc review is unwarranted because the Panel correctly resolved both issues.

The Timing of Notice: The Panel analyzed the text of subparagraph (*l*)(8)(A), its surrounding context, and Congress's intent, and unanimously concluded that effective notice may be given only after FDA approval. (Maj. Op. at 18.) That decision is faithful to the statutory text, which refers to notice of commercial marketing of "the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A) (emphasis added). A product is "licensed" only after FDA approval. It is also faithful to the statute as a whole, which uses the phrase, "the biological product that is the subject of" the subsection (k) application when it refers to the product pre-licensure, *e.g.*, 42 U.S.C. § 262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(3)(B)(ii)(I), (*l*)(3)(C), (*l*)(7)(B), and which suggests that licensure and commercial marketing will occur some six months apart, *compare* 42 U.S.C. § 262(k)(6)(A) *with* 42 U.S.C. § 262(k)(6)(C)(ii). And it is faithful to

Congress's desire to ensure "the existence of a fully crystallized controversy regarding the need for injunctive relief" before burdening the courts with applications for preliminary injunctions. (Maj. Op. at 17.)

Sandoz gave notice twice: on July 8, 2014 when FDA accepted its aBLA for review, and again on March 6, 2015 when FDA approved ZARXIO®. (*Id.* at 7.) The Panel unanimously held that only the second of these notices was legally operative. (*Id*. at 18, 19, 22.)

Sandoz now makes two arguments for why notice should not have to follow FDA approval. First, Sandoz argues that notice at the time of FDA approval is superfluous, because FDA licensure is itself a public act. (Sandoz Petition at 2-3, 9.) But the required notice is notice of the timing of first commercial marketing, which cannot be presumed merely from the grant of a license. It is also notice of the scope of that first commercial marketing: As the Panel noted, it is only upon FDA approval that "the product, its therapeutic uses, and its manufacturing processes are fixed." (Maj. Op. at 17.)

Second, Sandoz argues that the thirty-month stay of approval of a generic drug under the Hatch-Waxman Act confirms, by its absence in the BPCIA, that Congress did not intend litigation to delay approval or marketing of a biosimilar. (Sandoz Petition at 6.) The absence of a thirty-month stay under the BPCIA confirms only that Congress did not pattern this part of the BPCIA after the Hatch-

Waxman Act. Instead of conditioning FDA licensure on the outcome or pendency of patent litigation, Congress linked the Applicant's obligation to provide notice of commercial marketing to the event of FDA licensure. This makes sense for a statute that uses a standard of biosimilarity, rather than identity, under which the ultimately approved product may differ from the reference product in its structure, manufacture, and uses. Whereas the Hatch-Waxman Act maintains the status quo through a thirty-month stay of FDA approval, the BPCIA vests in the district courts the authority to determine whether to preserve the status quo beyond the 180-day notice period through a preliminary injunction sought by the RPS. Anticipating the increased burden and disruption this would create for the courts, Congress established a defined statutory window of no less than 180 days after FDA approval and before commercial marketing "during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product." (Maj. Op. at 17.)

The Injunction Pending Appeal: With its notice of appeal, Amgen sought an injunction pending appeal under Fed. R. App. P. 8(A), which the Court granted on May 6, 2015, to last "until this Court resolves the appeal." (Dkt. No. 105 at 1.) The Panel extended that injunction "through September 2, 2015," which is 180 days from Sandoz's operative March 6, 2015 notice. (Maj. Op. at 22, 25.) Amgen then sought an injunction during any en banc or subsequent proceedings, which

was denied. (Dkt. Nos. 124, 128.) Sandoz has begun marketing ZARXIO® in the United States.

Sandoz argues that in requiring it to wait until after September 2, 2015, the Panel majority entered an injunction that conflicts with governing authority, citing *Alexander v. Sandoval*, 532 U.S. 275 (2001) and *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). (Sandoz Petition at 12-14.). Not so. The Panel simply extended an existing injunction until the date on which Sandoz itself said it would first begin commercial marketing by virtue of its March 6, 2015 notice. Sandoz has never contended that an Applicant may give 180 days' notice of commercial marketing but then disregard that notice and begin marketing in fewer than 180 days. So Sandoz was "enjoined" from doing what it said it would not do. There is no *eBay* issue, because the initial injunction pending appeal was granted based on the traditional, four-factor equitable test of likelihood of success, irreparable harm, balance of the equities, and consideration of the public interest. (*See* Dkt. Nos. 56, 105.) Having determined that notice of commercial marketing is mandatory, having determined that notice must follow FDA licensure, and having found no dispute that Sandoz's March 2015 notice was effective pursuant to the Panel's interpretation of subparagraph 262(*l*)(8)(A), the Panel determined that Amgen's unfair competition claim was rendered moot. There was no violation

of the statute to remedy, and nothing in the Panel's exercise of discretion to extend the injunction is contrary to *Alexander*. (Maj. Op. at 22.)

* * * *

Amgen submits that there is no reason to rehear en banc whether effective notice under 42 U.S.C. § 262(*l*)(8)(A) may be given only after FDA approval, or whether Sandoz was properly enjoined from launching ZARXIO® until the date consistent with Sandoz's notice of first commercial marketing.

ARGUMENT

I. The Panel Correctly Held that Subparagraph 262(*l*)(8)(A) Requires Notice After FDA Licensure

Subparagraph (*l*)(8)(A) provides that "'[t]he subsection (k) applicant *shall* provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product *licensed* under subsection (k).'" (Maj. Op. at 15, quoting 42 U.S.C. § 262(*l*)(8)(A) (emphases added by Panel.)) Sandoz successfully argued to the district court that it could provide this 180 days' notice as soon as FDA accepted its BLA for review.

Relying on the statutory text and purpose, the Panel unanimously reversed the district court, holding that "[t]he statutory language compels" the conclusion that notice may be given only after FDA approval. (*Id.* at 16.) The Panel held:

> We therefore conclude that, under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product. The district court thus erred in

> holding that a notice of commercial marketing under paragraph (*l*)(8)(A) may effectively be given before the biological product is licensed, and we therefore reverse its conclusion relating to its interpretation of § 262(*l*)(8)(A) and the date when Sandoz may market its product.

(*Id.* at 18.) Each of Judges Newman and Chen joined this Part B.II.a. of the Panel opinion. (*See* Newman Op. at 2; Chen Op. at 1).

A. The Statutory Text Makes Clear That Notice May Be Given Only After FDA Licensure

As the Panel noted, the language of subparagraph (*l*)(8)(A) is unique. (Maj. Op. at 16). Everywhere else in subsection (*l*), the BPCIA refers to the proposed biosimilar as "the biological product that is the subject of" the subsection (k) application—this is true even when the statute discusses commercial marketing of that product. *E.g.*, 42 U.S.C. § 262(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(3)(B)(ii)(I), (*l*)(3)(C), (*l*)(7)(B). Only subparagraph (*l*)(8)(A) refers to "the biological product licensed under subsection (k)." The Panel appropriately inferred that Congress's use of a different term in this one circumstance was deliberate and meaningful. (Maj. Op. at 17) (citing *e.g.*, *Russello v. United States*, 464 U.S. 16, 23 (1983)). It is only after FDA approval that the product becomes "a product licensed under subsection (k)." "Licensed" means "[t]o whom or for which a licence has been granted; provided with a licence." 1 OXFORD ENGLISH DICTIONARY 245 (Oxford Univ. Press, Compact ed. 1971).

Three other aspects of the statute confirm this interpretation:

First, while subparagraph (*l*)(8)(A) is the only place within subsection (*l*) that the BPCIA uses the term "product(s) licensed," the statute uses that term elsewhere. Wherever it does so, it refers to a product that FDA has already licensed. *See*, *e.g.*, 42 U.S.C. § 262(d)(1), (i)(4), (k)(5)(C).

Second, the biosimilar interchangeability exclusivity provisions of 42 U.S.C. § 262(k)(6) suggest that approval and commercial marketing will occur approximately six months apart; exclusivity ends with the first to occur of five events, one of which is one year after commercial marketing and another of which is eighteen months after FDA approval if there is no subparagraph 262(*l*)(6) lawsuit. *Compare* 42 U.S.C. § 262(k)(6)(A) *with* 42 U.S.C. § 262(k)(6)(C)(ii).

Third, the contrary reading—that notice of commercial marketing may be given as soon as the Applicant files its aBLA—would render other statutory provisions unworkable. For example, subparagraph (*l*)(9)(A) refers to a period beginning with the provision of the aBLA and manufacturing information to the RPS under subparagraph (*l*)(2)(A), and ending with notice of commercial marketing under subparagraph (*l*)(8)(A). If the Applicant could give that notice as soon as it files its aBLA, the end of that period would precede its beginning, rendering the provision meaningless.

B. The Statutory Purpose Confirms That Notice Must Follow FDA Approval

The Panel further held that requiring pre-marketing notice to follow FDA

approval affords with Congress's intent. (Maj. Op. at 17.) It is only after licensure that "the product, its therapeutic uses, and its manufacturing processes are fixed." (*Id.*) On the other hand, when an applicant files its aBLA it does not even know whether, much less when, it will get approval. "The FDA could request changes to the product during the review process, or it could approve some but not all sought-for uses." (*Id.*) Only by receiving notice "after FDA licensure, once the scope of the approved license is known and the marketing of the proposed biosimilar product is imminent," can the RPS "effectively determine whether, and on which patents, to seek a preliminary injunction from the court." (*Id.*)

It is entirely consistent with the broader statutory purpose of the BPCIA that Congress created a 180-day notice period, after the controversy has been fully crystalized and marketing of the proposed biosimilar product is imminent, to permit the RPS to assess whether, and on which patents, to seek court intervention by motion for preliminary injunction. Anticipating the increased burden and disruption this new statutory scheme would create for the courts, Congress provided a period of time for the orderly resolution of these disputes to avoid forcing the RPS from having to seek a temporary restraining order to prevent a biosimilar's imminent launch.

C. Notice Given After FDA Approval Is Not Superfluous

Sandoz argues that requiring notice after FDA approval is "superfluous,"

because "FDA licensure of a biosimilar is a public act. There is no need for special 'notice' of it." (Sandoz Petition at 9.) That misstates the purpose of notice. The Applicant gives notice so that the RPS will know when the Applicant will commence marketing of the now-approved product, giving the RPS at least 180 days to seek a preliminary injunction. It cannot be presumed that commercial marketing will follow 180 days after approval: an Applicant might delay commercial marketing after licensure to await trial on the merits of a subparagraph 262(*l*)(6) patent litigation, for commercial reasons, for supply reasons, or even to wait for the expiration of a patent. If first commercial marketing is not imminent upon licensure, the BPCIA should not be interpreted to burden the court with an unnecessary (and perhaps not even ripe) application for an injunction.

Sandoz also argues that notice prior to FDA approval facilitates early litigation on all patents by lifting the bar to certain declaratory judgment actions in subparagraph 262(*l*)(9)(A), and that the RPS could seek a preliminary injunction even if notice could be effective prior to approval. (*Id.* at 7-8.) In addition to ignoring the words and context of the statute, that proves too much: If Congress merely wanted to ensure swift litigation of patent claims, it could have simply amended the Patent Act to make filing an aBLA a technical act of infringement, as it did in 35 U.S.C. § 271(e)(2)(C), and not created the patent-exchange provisions of subsection 262(*l*) at all. Instead, Congress created those elaborate provisions

and an at-least-180-day statutory period after approval and before commercial marketing in which the RPS can seek a preliminary injunction as needed.

D. Comparison With the Hatch-Waxman Act Confirms Only That the Panel Was Correct

Sandoz contends that requiring notice after FDA approval ensures that there will always be post-approval litigation, and that if Congress wanted to delay availability of biosimilar products beyond the regulatory exclusivity period pending the outcome of patent litigation it could have written something akin to the 30-month stay of approval of generic drugs under the Hatch-Waxman Act. (Sandoz Petition at 2, 6.) This, too, misperceives the balance that Congress struck.

Congress wanted an orderly presentation of injunction applications based not on conjecture but on fact, so that the courts could determine whether to maintain the status quo beyond the 180-day notice period based on a preliminary injunction standard rather than by statutory fiat. As the Panel stated, "Requiring that a product be licensed before notice of commercial marketing ensures the existence of a fully crystallized controversy requiring the need for injunctive relief. It provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product." (Maj. Op. at 17.) On the other hand, "If a notice of commercial marketing could be given at any time before FDA licensure," the RPS "would be left to guess the scope of the approved license and when commercial marketing would actually begin." (*Id.*)

Sandoz and its amici complain that requiring notice to be given after FDA approval effectively gives an RPS an additional 180 days of market exclusivity (Sandoz Petition at 6; Dkt. No. 139 at 7-9; Dkt. No. 140 at 9-10; Dkt. No. 150 at 3-4.) This complaint is ill-founded. Sandoz suggests that the Panel's interpretation is somehow inconsistent with provisions of the BPCIA that refer to "exclusivity," *e.g.* 42 U.S.C. § 262(m)(2)(A), but "exclusivity" in those provisions refers to the date when FDA approval may be "made effective," not to the date of commercial marketing, *see*, *e.g.*, 42 U.S.C. § 262(k)(7)(A). Indeed, the sole part of the statute that refers to both FDA approval and commercial marketing confirms that those two events will not be simultaneous and will likely be approximately six months apart. *Compare* 42 U.S.C. § 262(k)(6)(A) *with* 42 U.S.C. § 262(k)(6)(C)(ii).

As explained above, the language of the BPCIA makes clear that Congress chose to link the event of FDA approval to the Applicant's obligation to provide 180 days' notice of its first commercial marketing. Whether that notice comes immediately upon FDA approval or weeks or months or years after approval, it provides the RPS a 180-day period in which to seek a preliminary injunction and removes any remaining limitations to certain declaratory judgment actions for both parties. *See* 42 U.S.C. § 262(*l*)(8)(B), (*l*)(9)(A). Rather than imposing a two-and-a-half-year (thirty-month) stay of approval, Congress created a six-month (180-day) stay of commercial marketing, to give the district courts time, and authority,

to determine whether, on a motion for preliminary injunction, the status quo should be maintained until the outcome of patent litigation. Nothing about that 180-day stay upends or alters the Congressional balance; it is part of that balance.

II. The Panel Correctly Applied the Statute in Holding That Sandoz May Not Launch for 180 Days

Having held that Sandoz's March 6, 2015 notice of commercial marketing—given the day FDA approved ZARXIO®—was legally effective and that its July 2014 notice was ineffective, the Panel then extended the existing injunction through September 2, 2015, or 180 days after March 6th. (Maj. Op. at 19, 22.)

That decision does not warrant en banc review. The Panel limited the duration of the injunction pending appeal to the period when Sandoz itself said it would not begin commercial marketing if its March 6, 2015 notice were deemed the legally effective notice. When the Panel unanimously held that Sandoz's March 6, 2015 notice was effective, September 3rd became the soonest Sandoz could begin commercial marketing. Sandoz's counsel was clear on this point at oral argument: "Sandoz re-gave notice on the day of approval, and . . . six months from that would be September 2nd. That would be the outside date that any injunction against marketing could apply." Oral Argument at 35:41, *available at* http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-1499.mp3.

Indeed, the Panel shortened the injunction to that date. Whereas the Court's initial, May 6, 2015 injunction extended "until this Court resolves the appeal,"

encompassing proceedings up to issuance of the Mandate, the Panel terminated the injunction after September 2, 2015. When Amgen sought to further the injunction in light of the parties' petitions for rehearing en banc, its request was denied. And when September 2nd passed, Sandoz began commercial sales of ZARXIO®.

That Sandoz had to wait until that date is simply the consequence of the Panel's unanimous decision to give Sandoz the benefit of the March 6, 2015 notice that Sandoz itself had sought. Sandoz does not suggest, and has never suggested, that an Applicant that gives 180-day notice under subparagraph (*l*)(8)(A) may then nonetheless begin marketing in fewer than 180 days.

Instead, Sandoz asserts that the Panel's decision conflicts with *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) and *Alexander v. Sandoval*, 532 U.S. 275 (2001). It conflicts with neither.

Sandoz characterizes *eBay* as holding that an injunction based on a "statutory violation" must meet the four-factor equitable test for an injunction. *eBay* actually held that a patent holder who proves infringement must still meet that four-factor test to obtain a permanent injunction. (Sandoz Petition at 13-14.) Whether that rule applies to a 180-day period embodied in the statute itself is an open question, but not one presented by this case: this Court granted its May 6, 2015 injunction pending appeal only after the parties briefed the four-factor equitable test, and denied a bond only after further briefing on that issue.

Nor is there an *Alexander* issue here. That case addressed implied private rights of action to enforce a statute that otherwise vested enforcement authority in a Federal agency. In a part of the opinion joined by all three Panel members, the Panel treated Amgen's unfair competition law claim as asserting, in part, "that Sandoz violated the BPCIA by giving a premature, ineffective, notice of commercial marketing under § 262(*l*)(8)(A) in July 2014, before FDA approval in March 2015." (Maj. Op. at 22.) The Panel then declared that counterclaim to be moot in light of Sandoz's subsequent March 6, 2015 notice and the injunction through September 2, 2015, and dismissed Amgen's unfair-competition claim as therefore "moot":

> As indicated, under our interpretation of the BPCIA, the July 2014 notice is ineffective, and Sandoz gave the operative notice on March 6, 2015. Thus, as we have indicated, Sandoz may not market Zarxio before 180 days from March 6, 2015, *i.e.* September 2, 2015. And, as indicated below, we will extend the injunction pending appeal through September 2, 2015. Amgen's appeal from the dismissal of its unfair competition claim based on the alleged violation of § 262(*l*)(8)(A) is therefore moot.

(*Id.*) The Panel properly used its discretionary power to preserve the status quo through the 180-day notice period as given by Sandoz. Having found no violation of the BPCIA in Sandoz's March 6, 2015 notice, there was no remedy to grant Amgen. The injunction granted by the Panel therefore fails even to raise the need to consider *Alexander*. The issue of a private right of action may very well be the

subject of this Court's attention in such subsequent cases; Sandoz's petition for rehearing, however, is not an appropriate vehicle for it.

CONCLUSION

Amgen respectfully submits that on the first of the two issues Sandoz raises, whether effective notice under subparagraph (*l*)(8)(A) may be given before or only after FDA approval, the Panel correctly and determined that notice must follow FDA approval. There is no reason for this Court to review that unanimous Panel decision en banc. Amgen further submits that the second issue—whether Sandoz was properly enjoined from commercial marketing through September 2, 2015—is subsumed by the first issue. If only Sandoz's March 6, 2015 notice was effective, as the full Panel found, then the soonest Sandoz could begin marketing was September 3, 2015, and marketing has in fact has begun. Nothing about ensuring that Sandoz complied with its own notice warrants en banc review. The Court should deny Sandoz's petition.

Dated: September 8, 2015

Respectfully submitted,

/s/ Nicholas Groombridge

Nicholas Groombridge
Eric Alan Stone
Jennifer H. Wu
Jennifer Gordon
Peter Sandel
Michael T. Wu
Arielle K. Linsey
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Vernon M. Winters
Alexander D. Baxter
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, CA 94104
(415) 772-1200

Wendy A. Whiteford
Lois M. Kwasigroch
Kimberlin L. Morley
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

Attorneys for Plaintiffs-Appellants

CERTIFICATE OF SERVICE

I hereby certify that on this 8th of September, 2015, I caused the foregoing Response of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited to Defendant-Appellee Sandoz's Petition Rehearing En Banc to be filed with the Clerk of the Court using the CM/ECF system. I also caused a true and correct copy of Response of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited to Defendant-Appellee Sandoz's Petition Rehearing En Banc to be electronically served on Defendant-Appellee Sandoz Inc.'s counsel of record, pursuant to agreement of the parties, as follows:

Deanne E. Maynard
(dmaynard@mofo.com)
Marc A. Hearron
(mhearron@mofo.com)
Joseph R. Palmore
(jpalmore@mofo.com)
MORRISON & FOERSTER LLP
2000 Pennsylvania Ave., N.W.
Suite 6000
Washington, D.C. 20006

Rachel Krevans (rkrevans@mofo.com)
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105

COUNSEL PRESS