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

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CERTIFICATE OF INTEREST

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

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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

   AMGEN INC.

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

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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,

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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:

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