No. 2024-1936

In the United States Court of Appeals for the Federal Circuit

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., and TEVA PHARMACEUTICALS USA, INC.,

Plaintiffs-Appellants,

v.

AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, and AMNEAL PHARMACEUTICALS INC.,

Defendants-Appellees.

Appeals from the U.S. District Court for the District of New Jersey, No. 23-cv-20964, Judge Stanley R. Chesler.

AMICUS BRIEF OF SANDOZ INC. IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

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September 5, 2024

CERTIFICATE OF INTEREST

Case No:	No. 2024-1936
Short Case Caption:	Teva Branded Pharmaceuticals R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC
Filing Party/Entity:	Sandoz Inc.

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Date: September 5, 2024

Signature: */s/ Laura A. Lydigsen*

Name: Laura A. Lydigsen

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☒ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Sandoz Inc.		Sandoz AG, Sandoz Group AG

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None.

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b). ☒ None/Not Applicable
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Abbreviation	Full Description
30-month stay	Stay of FDA approval of an ANDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) under which "approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under [21 U.S.C. § 355(j)(2)(B)(i)]"
Amneal	Defendants-Appellees Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc.
ANDA	Abbreviated New Drug Application
BlBr.	Appellant Teva's Opening Brief, ECF No. 34
BPCIA	Biologics Price Competition and Innovation Act of 2009
FDA	U.S. Food and Drug Administration
Orange Book	FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*
Sandoz	Amicus Curiae Sandoz Inc.
Teva	Plaintiffs-Appellants Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc.
USPTO	U.S. Patent and Trademark Office

I. INTRODUCTION AND STATEMENT OF INTEREST OF AMICUS CURIAE SANDOZ INC.[1]

Amicus curiae Sandoz Inc. is a global leader in generic and biosimilar medicines, with the purpose of pioneering access to drugs for patients. Sandoz's efforts to provide quality generics to U.S. patients routinely necessitate that it litigate patent disputes in U.S. courts under the Hatch-Waxman Act. Since 2003 when Sandoz began developing generics, it has been named as a party in hundreds of such litigations.

Sandoz agrees with and supports the district court's well-reasoned decision. Sandoz submits this amicus brief to address a consequence of improper Orange Book listings that has not received sufficient attention: the owner of a patent listed in the Orange Book—whether or not that patent is properly listed—is entitled to, upon a showing of infringement, an order that FDA approval of an ANDA not be effective until the patent expires. 35 U.S.C. § 271(e)(4)(A). Courts have treated this remedy as automatic, without consideration of any of the equitable factors applicable under *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). Without FDA approval, the ANDA applicant cannot launch its product—

[1] Under Fed. R. App. P. 29 (a)(4)(E), Sandoz notes that no party's counsel authored any part of this brief, and no one other than Sandoz and its counsel contributed money to fund its preparation or submission. All parties consented to the filing of this brief. Fed. R. App. P. 29(a)(2).

irrespective of the equitable factors that courts are required to apply in every other patent case under *eBay*. This powerful remedy should not be available for just any patent, especially one that is tangential, minute, or incidental to the drug product.

Because this powerful remedy afforded to any patent listed in the Orange Book under 271(e)(4)(A) can delay Americans' access to lower-cost generic drugs—regardless of the public interest in obtaining those drugs and any other equitable considerations that would need to be proven before an injunction were entered in any other non-Hatch-Waxman context—courts should not construe the listing statute broadly, as Teva seeks. The district court's reading of the listing statute as limited to drug patents best comports with the overall Hatch-Waxman scheme, and its decision should be affirmed.

II. ARGUMENT

The district court held that particular device patents may not be listed in the Orange Book because a patent is only eligible for listing under 21 U.S.C. § 355(b)(1)(A)(viii) if it "claim[s] the drug for which the applicant submitted the application" or a method of using such a drug. Appx33; Appx34 n.3; Appx35; Appx39-40. Teva complains that the district court's interpretation will upset the balance struck by the Hatch-Waxman Act by "narrowing" and "shrink[ing]" the scope of patents eligible for listing. BlBr. 2, 36, 51-53. Teva gets it backwards; a literal reading of the listing statute is precisely what is demanded to balance the

broad injunctive relief an Orange Book-listed patent is afforded under the Hatch-Waxman Act.

A. By Listing a Patent in the Orange Book, a Patentee Gets a Powerful Remedy: That Patent Can Serve as the Basis of an Order Blocking FDA Approval of an ANDA Until Patent Expiration

The Hatch-Waxman Act provides a unique injunctive remedy that courts typically grant without consideration of the *eBay* factors governing injunctions in every other type of patent case. Under 35 U.S.C. § 271(e)(4), for a small molecule drug that is not yet commercially marketed,[2] the "remedies which may be granted by a court for an act of infringement described in [section 271(e)(2)]" are the following:

> (A) the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
>
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . . .,

35 U.S.C. § 271(e)(4).

On top of 271(e)(4)(B)'s traditional injunctive relief analysis, the Hatch-Waxman Act adds the remedy of 271(e)(4)(A)—a powerful mechanism that

[2] The other remedies in 35 U.S.C. § 271(e)(4) are inapplicable because they require commercial launch (subpart (C)) or apply only to large molecule, biological products (subpart (D)).

prevents the FDA from approving a generic drug found to infringe a patent brought under 35 U.S.C. § 271(e)(2). *See In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1367 (Fed. Cir. 2008). Subpart (A)'s prohibition on FDA approval forecloses commercial marketing, use, offer for sale, and sale of the drug and thus has been repeatedly recognized as establishing a *de facto* injunction, even though subpart (A) does not expressly use the word "injunctive" like subpart (B). *See, e.g.*, *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1123, 1139 (Fed. Cir. 2018) (affirming injunctive relief granted under the court's general powers as "consistent with" the remedies available under section 271(e)(4)(A)); *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1367 (Fed. Cir. 2014) (Moore, C.J., dissenting) ("[S]ince the generic can't launch without FDA approval, the statute creates a *de facto* injunction."); *Alcon, Inc. v. Teva Pharms. USA, Inc.*, No. 06-234, 2010 WL 3081327, at *3 (D. Del. Aug. 5, 2010) (denying injunction under subpart (B) based on the *eBay* factors because "a remedy exists under 35 U.S.C. § 271(e)(4)(A)" that "effectively precludes practice of the . . . patent outside of the context of experimentation").

The *de facto* injunction in section 271(e)(4)(A) is particularly powerful because, unlike the 271(e)(4)(B) injunction, several courts have held that it "is automatic under the statute—not requiring a showing of the permanent injunction

factors required in *eBay*."[3] *Actavis Labs. FL, Inc. v. United States*, 161 Fed. Cl. 334, 364 (2022). In *eBay*, the Supreme Court based the application of those equitable factors on the Patent Act's general injunction provision, 35 U.S.C. § 283, which expressly states that injunctions may be granted "in accordance with the principles of equity." 547 U.S. at 391-92 (quoting 35 U.S.C. § 283). By contrast, section 271(e)(4)(A)'s *de facto* injunction provision lacks any such reference to "principles of equity." Subpart 271(e)(4)(A) differs from section 283 and subpart 271(e)(4)(B) in another important way. Unlike section 283 and subpart (B), which each use the permissive "may," subpart (A) says that "the court shall order" the FDA not to grant approval until expiration of the infringed patent—compulsory-type language some courts have pointed to as reason to dispense with the *eBay* factors.[4] *See, e.g.*, *Braintree*, 749 F.3d at 1367 (Moore, C.J., dissenting).

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[3] Whether the section 271(e)(4)(A) remedy is automatic and thus bypasses consideration of equitable factors has not been directly before this Court.

[4] Although few courts have directly evaluated the differences in the availability of injunctive relief under both section 271(e)(4)(A) and (B), most that have considered section 271(e)(4) only applied the equitable *eBay* factors in connection with subpart (B) or the court's general powers. *E.g.*, *Endo Pharms. Inc. v. Amneal Pharms LLC*, No. 12-8115, 2016 WL 1732751, at *4 (S.D.N.Y. Apr. 29, 2016); *Janssen Prods., L.P. v. Lupin Ltd.*, 109 F. Supp. 3d 650, 708-09 (D.N.J. 2014), *modified on other grounds*, No. 10-5954, 2016 WL 1029269 (D.N.J. Mar. 15, 2016); *Alcon*, 2010 WL 3081327, at *1-2; *contra SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1045-52 (N.D. Ill. 2003), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005).

B. The District Court Correctly Interpreted the Listing Statute Given the Significant Injunctive Relief That Attaches to Orange Book Listed Patents

Statutory language must be construed "in [its] context and with a view to [its] place in the overall statutory scheme." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citation omitted). The listing statute, 35 U.S.C. § 355, is no exception.

Teva complains that the district court's holding regarding the Hatch-Waxman Act's listing statute "shrink[s] the Orange Book" by "narrow[ing]" the scope of listable patents. BlBr.2, 36. But given the broad, automatic remedies available under the Act, any *de facto* injunction in section 271(e)(4)(A) should only be available for patents that cover the drug itself, not a tangential device, minute component, or *de minimis* infringement. For such patents, an injunction would be inequitable, and therefore unachievable, in any other non-Hatch-Waxman context where a patentee would have to prove the *eBay* factors for an injunction to issue.

Several courts and scholars have also acknowledged the inequitable results that follow where section 271(e)(4)(A)'s *de facto* injunction is applied to peripheral patents that at best cover a *de minimis* use or a minor component of the overall drug product. In her dissent in *Braintree*, Chief Judge Moore observed that she "[didn't] like th[e] result" of the statute, which "commands" an injunction

"even if there is only a single infringement." 749 F.3d at 1367 (Moore, C.J., dissenting). In *SmithKline*, Judge Posner was troubled by SmithKline wielding its patent for paroxetine hydrochloride hemihydrate against Apotex's anhydrate product based on an argument that Apotex's product, once sold, might contain some small percentage of the infringing hemihydrate. 247 F. Supp. 2d at 1045-46. Judge Posner wrote that enjoining Apotex's sales of the anhydrate based on a small, unwanted percentage of the hemihydrate "would be a travesty of equity." *Id.* These types of troubling and inequitable results will only proliferate if the listing statute is interpreted to permit listing any patent that may be infringed.

The inequity of an automatic injunction is further illustrated by comparison to how courts apportion damages in non-Hatch-Waxman patent infringement proceedings. When a patent covers only one component of a multi-component product, courts award damages based on the incremental value attributable to the invention through apportionment. *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1326 (Fed. Cir. 2014) ("[A] patentee must take care to seek only those damages attributable to the infringing features."). But courts cannot apportion an injunction. An automatic injunction for patents that do not cover the drug is equivalent to basing a damages award on the entire value of a car for a patent that covers the cupholder.

As a frequent Hatch-Waxman litigant, Sandoz regularly finds itself defending against Orange Book-listed patents that bear, at best, a tenuous relationship with the drug product for which they are listed. In one recent Hatch-Waxman example, this Court recently affirmed a judgment of invalidity in Sandoz's favor for four Orange-Book listed patents directed to methods for administering pirfenidone to patients with abnormal biomarkers. *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368, 1371, 1378 (Fed. Cir. 2022). Even though only roughly 4% of patients have the biomarkers that might implicate Genentech's patents (the brand manufacturer), Genentech listed each in the Orange Book and sought an order to prevent FDA approval—and thus all sales—of Sandoz's ANDA for a generic version of Esbriet®. *See Genentech, Inc. v. Sandoz, Inc.*, 592 F. Supp. 3d 355, 367-68 n.6 (D. Del. 2022). If Genentech had won that dispute and obtained a remedy under section 271(e)(4)(A), Sandoz would have been blocked from FDA approval until those patents expired in 2029 (instead of its actual launch in 2022), delaying the U.S. healthcare system the benefit of Sandoz's lower cost generic alternative for almost 7 years based on patents that cover less than 4% of patients.

Teva complains that the Court's interpretation of the listing statute "disrupt[s] the balance Congress struck." BlBr.55. Not so. It is Teva's interpretation of the listing statute that disrupts that balance by expanding the

universe of patents on which a branded drug patentee may contend it is entitled to automatic injunctive relief versus having to demonstrate the necessary proofs before being eligible for this extraordinary equitable relief. As Judge Posner put it, such a result would be a "travesty of equity." *SmithKline*, 247 F. Supp. 2d at 1045-46. Tellingly, the BPCIA establishes a similar scheme as the Hatch-Waxman Act, but lacks a provision analogous to section 271(e)(4)(A)'s broad *de facto* injunction, prompting courts to consistently apply *eBay* to determine the appropriateness of an injunction based on the particular patents found infringed.[5] *E.g.*, *In re Aflibercept Patent Litig.*, No. 22-0061, 2024 WL 3177913, at *5 (N.D.W. Va. Jun. 11, 2024).

C. Expanding the Listing Statute Would Disserve the Hatch-Waxman System and Not Solve the Problems that Teva Describes

Despite litigating as a branded pharmaceutical patentee in this case, Teva puts its "generic" hat on to contend that its expansive construction of the listing statute (1) provides generics with notice of all relevant patents and (2) eliminates

[5] The BPCIA provides for injunctive relief in addition to that available under the traditional four-factor *eBay* test only when the multiple prerequisites set out in 271(e)(4)(D) are met, none of which are required in 271(e)(4)(A). 35 U.S.C. § 271(e)(4). Actions meeting these criteria are exceedingly rare—to date, no court has issued an injunction under 271(e)(4)(D). Further, the injunction narrowly prohibits "infringement" and, unlike 271(e)(4)(A), does not broadly prevent the FDA from approving the application.

post-launch litigation and damages exposure. BlBr.54-55. Teva is wrong on both accounts.

First, a broadly construed listing statute would not provide any more notice of relevant patents than what generics can obtain through publicly accessible databases. The patents listed in the Orange Book are not the only patents that a brand company may assert against a generic applicant, even under Teva's expanded construction of the listing statute. Indeed, FDA specifically recommends that generic applicants search for relevant, non-Orange Book listed patents.[6] Such a search would not be necessary if the Orange Book was intended to be the sole mechanism through which information regarding all potentially assertable patents was available to the generic drug manufacturer. This is not now, nor has it ever been, the case.

Second, expanding the listing statute would not eliminate post-launch patent disputes. Teva suggests that an unlisted patent could get asserted following a

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[6] *See* Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50346 (Oct. 3, 1994) (codified at 21 C.F.R. § 314.94) ("FDA, however, believes it would be prudent for applicants to conduct patent searches if possible. A patent search could reveal the existence of an unlisted, but valid, patent and thus prevent an unnecessary expenditure of resources by applicants and FDA on a product that might not be marketable. A patent search might also enable ANDA applicants to avoid unnecessary patent infringement litigation.").

generic launch, exposing that generic to post-launch proceedings and a claim for damages. BlBr.54-55. Sandoz agrees that the proliferation of post-launch proceedings is problematic as it is increasingly a calculated strategy adopted by brand manufacturers to assert patents, oftentimes in a serial manner, aimed at securing multiple bites at the apple to obtain an injunction or monetary damages. Not only does this behavior, one which is entirely within the brand's control, have the impact of increasing costs for generic drug companies, it also extends the period of risk and uncertainty for generic manufacturers in contravention of the policy objectives of the Hatch-Waxman system. But, as illustrated further below, expanding the scope of patents that can be listed in the Orange Book does nothing to solve that problem.

Post-launch proceedings can occur regardless of whether a patent is listed in the Orange Book—that is, a brand company can list a patent in the Orange Book and hold it in reserve until after a generic launch. The Hatch-Waxman dispute between Genentech and Sandoz concerning pirfenidone again exemplifies this problem. There, Genentech asserted over 20 patents against Sandoz but elected not to assert a particular Orange Book-listed formulation patent. When the district court ordered that the case be narrowed, Genentech selected its best patents for trial and promised that it would not hold other parts of the case "in ready reserve." *Genentech, Inc. v. Sandoz, Inc.*, No. 19-0078, ECF No. 387-1, Ex. C, at 37:16-

38:14 (D. Del. Oct. 22, 2021). Sandoz launched shortly after the district court found those "best" patents invalid, not infringed, or both, which the Federal Circuit affirmed. *Genentech*, 55 F.4th at 1381. Yet following Sandoz's launch, Genentech asserted its held-back formulation patent, suing in a new venue and seeking damages at a jury trial. *Genentech, Inc. v. Sandoz, Inc.*, No. 23-4085, ECF No. 1 (D.N.J. Jul. 31, 2023). Nothing about this held-back patent being listed in the Orange Book prevented Genentech from engaging in serial litigation and bringing a post-launch proceeding against Sandoz seeking damages.

As another example, brand companies also have patent prosecution tools that allow them to delay notice of their patents irrespective of the breadth of the listing statute. For example, a brand can elect not to have its patent applications published by the USPTO and/or to protract patent prosecution until a generic launch is imminent. *See* 37 C.F.R. § 1.213. These tactics have the impact of shielding potentially relevant patents from public notice therefore extending the period of litigation risk and uncertainty for the generic manufacturer well beyond the 30-month stay provided for under the Hatch-Waxman Act. Expanding the listing statute as Teva proposes would do nothing to solve this problem.[7]

[7] The BPCIA strongly suggests that Congress does not place much weight on the public notice function of patent listing requirements. Although biosimilars have the Purple Book, which is somewhat analogous to the Orange Book, it is not

* * *

At bottom, seeking to enhance notice and to eliminate post-launch proceedings are laudable goals. But, as explained above, construing the listing statute expansively will not promote those goals. If anything, expanding the listing statute will only increase the scope of patents that can serve as the basis for the powerful remedy of section 271(e)(4)(A), making it easier for brand companies to block the launch of a generic product on the basis of patents that otherwise could not have served as the basis for a permanent injunction under *eBay*.

Even if a broader listing statute meant greater notice and eliminated post-launch proceedings (it does not), those are not the only considerations for a generic drug company in deciding whether to invest in a litigation. Pharmaceutical patent litigation is extremely costly for generic companies, especially when compared to the relative margins on generic versus branded pharmaceuticals. Because of those cost concerns, generic drug companies must prioritize the products in which they invest. Generic companies may elect not to devote resources to pursuing a product where the potential litigation outcomes do not warrant the costs. Patent litigation is already an asymmetrical dispute in that a challenger needs to clear all asserted

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comprehensive and will be empty of patent information for at least the first biosimilar filer. *See* 42 U.S.C. § 262(k)(9)(A)(iii) (requiring submissions for listing on the Purple Book *after* patent dance exchanges).

claims, whereas a patent owner needs to win on just one claim. That asymmetry is exacerbated when the Orange Book lists several patents for a product and any single claim of those patents could serve as the basis of a 271(e)(4)(A) *de facto* injunction. Foreclosing the entire market based on a single patent claim is a powerful remedy, especially when that foreclosure is based on a patent that would not otherwise warrant an injunction under the *eBay* factors, such as the patent described in our pirfenidone example that covers only 4% of the market. This combination of resource limitations, asymmetrical litigation hurdles, and powerful foreclosure remedies can drive generic companies to enter into settlements as a risk mitigation strategy, as opposed to pushing forward in challenging what would otherwise be vulnerable patents or patents on which a financial remedy is the primary exposure. Thus, a broader listing statute, which increases the number of patent claims that can serve as the basis of a 271(e)(4)(A) *de facto* injunction, may deter generic companies from investing in a product and/or litigating to a final resolution, thereby depriving the U.S. healthcare system and the public of access to new, lower-cost pharmaceutical products.

III. CONCLUSION

The Court should endorse the district court's interpretation of 21 U.S.C. § 355(b)(1)(A)(viii) that patents eligible for listing in the Orange Book are limited to those that "claim[] the drug for which the applicant submitted the application" or

a method of using such a drug. Appx33. Based on this interpretation, the Court should affirm judgment in favor of Amneal and hold that Teva's patents were improperly listed in the Orange Book.

September 5, 2024

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of September 2024, I caused the foregoing brief to be electronically filed using the CM/ECF system, which will send notification of such filing to all parties of record.

September 5, 2024

/s/ Laura A. Lydigsen
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Attorney for Amicus Curiae Sandoz Inc.

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