No. 23-1186

United States Court of Appeals for the Federal Circuit

JAZZ PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

AVADEL CNS PHARMACEUTICALS, LLC,

Defendant-Appellee.

Appeal from the U.S. District Court for the District of Delaware,
No. 1:21-cv-00691-GBW, Hon. Gregory B. Williams

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January 13, 2023

Claim 1 of U.S. Patent No. 8,731,963 provides (Appx98-99 (emphases added)):

1. A *computer-implemented system* for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, comprising:

one or more *computer memories* for storing a single computer database having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields;

said prescription fields, contained within the database schema, storing prescriptions for the prescription drug with the potential for abuse, misuse or diversion, wherein the prescription drug is sold or distributed by a company that obtained approval for distribution of the prescription drug;

said patient fields, contained within the database schema, storing information sufficient to identify the narcoleptic patient for whom the company's prescription drug is prescribed;

said prescriber fields, contained within the database schema, storing information sufficient to identify a physician or other prescriber of the company's prescription drug and information to show that the physician or other prescriber is authorized to prescribe the company's prescription drug;

a *data processor* configured to:

process a database query that operates over all data related to the prescription fields, prescriber fields, and patient fields for the prescription drug; and

reconcile inventory of the prescription drug before the shipments for a day or other time period are sent by using said database query to identify information in the prescription fields and patient fields;

wherein the data processor is configured to process a second database query that identifies that the narcoleptic patient is a cash payer and a physician that is interrelated with the narcoleptic patient through the schema of the single computer database;

said identifying that the narcoleptic patient is a cash payer by said second database query being an indicator of a potential misuse, abuse or diversion by the narcoleptic patient and being used to notify the physician that is interrelated with the narcoleptic patient through the schema of the single computer database.

CERTIFICATE OF INTEREST

Case Number: 23-1186

Short Case Caption: *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC*

Filing Party/Entity: Avadel CNS Pharmaceuticals, LLC, Appellee

I certify the following information is accurate and complete to the best of my knowledge.

Date: January 13, 2023 Signature: */s/ Kenneth G. Schuler*
Name: Kenneth G. Schuler

1. Represented Entities. Provide the full names of all entities represented by undersigned counsel in this case.

Avadel CNS Pharmaceuticals, LLC

2. Real Party in Interest. 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.

3. Parent Corporations and Stockholders. 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.

Avadel CNS Pharmaceuticals, LLC is wholly owned subsidiary of Avadel US Holdings, Inc., which is a wholly owned subsidiary of Avadel Pharmaceuticals plc. Avadel Pharmaceuticals plc is a publicly traded company with no parent corporation and no publicly traded company owning more than 10% of its stock.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

Latham & Watkins LLP: Franco Benyamin, Bornali Rashmi Borah (no longer with firm), Ian Conner, Alan Devlin, Alex M. Grabowski, Yi Ning, Sarah H. Wang, Herman Yue

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DLA Piper, LLP: Angela Whitesell

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).

Avadel CNS Pharmaceuticals, LLC, et al. v. Jazz Pharmaceuticals, Inc., et al., No. 1:22-cv-00487-GBW (D. Del.) (filed Apr. 14, 2022)

Jazz Pharmaceuticals, Inc., et al. v. Avadel CNS Pharmaceuticals, LLC, No. 1:21-cv-00941-GBW (D. Del.) (filed Aug. 4, 2021)

Jazz Pharmaceuticals, Inc., et al. v. Avadel CNS Pharmaceuticals, LLC, No. 1:21-cv-01138-GBW (D. Del.) (filed Aug. 4, 2021)

Jazz Pharmaceuticals, Inc., et al. v. Avadel CNS Pharmaceuticals, LLC, No. 1:21-cv-01594-GBW (D. Del.) (filed Nov. 10, 2021)

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None/Not Applicable.

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STATEMENT OF RELATED CASES

This appeal arises from a pending civil action in the U.S. District Court for the District of Delaware. *See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, No. 1:22-cv-00941-GBW (D. Del.). This is the only appeal from that civil action. No other appeal from that action has previously arisen in this Court or any other appellate court.

STATEMENT OF THE ISSUES

The dispositive issue is: Whether the district court properly directed Appellant Jazz Pharmaceuticals, Inc. ("Jazz") to delist U.S. Patent No. 8,731,963 ("the '963 patent") from the FDA's Orange Book—under a statute providing for the delisting of any patent that does not claim a "drug" or a "method of using" a drug (21 U.S.C. § 355(c)(3)(D)(ii)(I))—because Jazz's '963 patent claims "computer-implemented system[s]" (Appx98), not a drug or a method of using a drug.

Jazz raises the following issues:

1. Whether the delisting statute, which expressly turns on what a "patent … claim[s]" (21 U.S.C. § 355(c)(3)(D)(ii)(I)) does not incorporate patent law claim construction principles.

2. Whether the delisting statute, which creates a right to seek delisting of any Orange Book-listed patent that "does not claim" either a drug or a method of using a drug (*id.*), requires historical examination of whether Jazz properly listed the patent in the first instance.

3. Whether the '963 patent claims—which recite "computer-implemented system[s]" (Appx98)—are actually method claims, not system claims.

INTRODUCTION

Appellee Avadel CNS Pharmaceuticals, LLC ("Avadel") has spent years and hundreds of millions of dollars developing a novel narcolepsy drug requiring only a single dose at bedtime. For patients suffering from narcolepsy, that achievement represents a life-changing improvement over Jazz's marketed drugs, which require narcolepsy patients to wake in the middle of the night to take a second dose. But patients cannot yet get Avadel's drug. Jazz automatically blocked FDA approval by improperly listing one of its patents—the '963 patent at issue in this appeal—in the FDA's "Orange Book" (a compendium of patents related to FDA-approved drugs) and then filing suit.

The district court correctly ordered Jazz to remove that barrier. By statute, the '963 patent must be delisted from the Orange Book unless it claims a drug or method of using a drug. 21 U.S.C. § 355(c)(3)(D)(ii)(I). And the '963 patent claims neither—it claims a "computer-implemented system." Appx98. The district court correctly construed Jazz's patent claims as being directed to a system (not a drug method-of-use) and thus properly held that Jazz's patent must be removed from the Orange Book. Jazz's appeal asks this Court to disregard the plain statutory language and plain claim language, all for the purpose of keeping Avadel's superior medication off the market.

The FDA treats "its duties with respect to Orange Book listings [as] purely ministerial." *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir. 2003). That is, the FDA "publish[es] submitted patent information" in the Orange Book without "review[ing] the merits of the patent information provided." *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008). Abuse of the FDA's ministerial listing regime by companies like Jazz led Congress to counter that malfeasance by statute. In 2003, Congress authorized certain patent-infringement defendants to file counterclaims seeking removal of patents listed in the Orange Book if the listed patent "does not claim either … the drug for which the application was approved" or "an approved method of using the drug." 21 U.S.C. § 355(c)(3)(D)(ii)(I).

The district court correctly ordered Jazz to remove the '963 patent from the Orange Book because it claims neither a "drug" for which an FDA new drug application was approved nor an "approved method of using" such a drug. *Id.* In doing so, the district court correctly applied this Court's teaching that these statutory inquiries are "issues of patent law," *Apotex*, 347 F.3d at 1344, and followed ordinary patent-law principles in construing the claims of the '963 patent. The court correctly held that the '963 patent—which claims a "computer-implemented system" for monitoring the distribution of a drug, Appx98—does not claim either a drug or a method for using a drug. It therefore granted judgment to Avadel on its counterclaim and issued a delisting injunction.

Jazz's opening brief challenging that injunction strays from the statutory text and seeks to confuse a clear legal framework. First, Jazz suggests that the district court erred by treating the question whether the '963 patent "claim[s] … an approved method of using [a] drug," as a question of patent law. Jazz contends that "Congress did *not* intend to import patent law" with respect to the listing and delisting of patents in the Orange Book. Opening Brief ("OB") 22 (citation omitted). That is wrong: Whether a listed patent claims a "drug" or a "method of using that drug" raises "issues of patent law." *Apotex*, 347 F.3d at 1344. Furthermore, Jazz's argument on this score is forfeited: Jazz persuaded the district court that delisting could not be resolved without claim construction (delaying resolution for over a year) and never argued that patent law does not govern. And in all events, under the plain terms of the delisting statute, the '963 patent does not claim a "method of *using [a] drug*," as the FTC explained in its amicus brief in the district court.

Second, Jazz asserts that its initial listing of the '963 patent in the Orange Book was proper. That, too, is wrong. As a system patent, the '963 patent was improperly listed under the plain terms of the listing statute and regulations. But, as the district court observed, that is irrelevant. The delisting statute requires delisting where a patent does not claim a drug or a method of using a drug; it does not involve historical analysis of whether the patent was properly listed in the first place.

Jazz's contrary argument rests on an unsupportable view of the listing scheme, leading to the absurd conclusion that *any* patent previously listed in the Orange Book is shielded from delisting so long as it is not a manufacturing "[p]rocess patent[]" or a patent "claiming packaging, … metabolites, [or] … intermediates." OB50 n.6 (first alteration in original) (quoting 21 C.F.R. § 314.53(b)(1)). That would exempt from delisting all manner of patents that do not claim a "drug" or a "method of using [a] drug," thus perpetuating the ill effects of the very abuse Congress sought to stop. Nor does rejection of Jazz's position require retroactive application of the Orange Book Transparency Act (OBTA) of 2020, which did not change the operation of the delisting statute.

Third, Jazz only briefly challenges the district court's claim construction, contending that the '963 patent recites method claims. The claim language refutes that argument: it recites a "computer-implemented system" (Appx98 (cl. 1)), not a method. It is no wonder that Jazz spends little time on this argument.

At their core, Jazz's principal arguments attempt to shield a routine patent inquiry—what does the '963 patent claim?—from judicial scrutiny. Jazz's general view seems to be that this Court and the district court should hand off that patent-law inquiry to the FDA. But the FDA's statutory role is "purely ministerial," *Apotex*, 347 F.3d at 1347, and it is the district court's job to resolve in the first instance any dispute as to whether a patent listed in the Orange Book claims either a "drug" or a

"method of using [a] drug." That is not a close question here. The district court rightly concluded that the '963 patent—which is directed to a computer system—claims neither of those things.

This Court should affirm and immediately lift the stay pending appeal, allowing the district court's ruling to take effect so that narcolepsy patients can gain access to Avadel's superior medication.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

This case arises from certain provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, widely known as the Hatch-Waxman Act. *See* Pub. L. No. 98-417, 98 Stat 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271). In that legislation, Congress sought to "further[] drug competition" and provide "special procedures for identifying, and resolving, … patent disputes" in connection with the approval of new pharmaceutical products. *FTC v. Actavis, Inc.*, 570 U.S. 136, 142-43 (2013).

1. New Drug Approval And The Orange Book

Under the Hatch-Waxman Act, a pharmaceutical company wishing to market a new drug must "submit[] to the FDA a new drug application ('NDA')." *Celgene Corp. v. Mylan Pharms. Inc.*, 17 F.4th 1111, 1117 (Fed. Cir. 2021). The NDA must "contain the drug's labeling and directions for use but also must contain extensive

information on clinical trials showing that the drug is safe and effective for its labeled use." *Id.*; *see* 21 U.S.C. § 355(b)(1)(A).

Once an NDA has been approved, and the drug for which that application has been marketed, the Hatch-Waxman Act provides two different avenues by which potential competitors can obtain FDA approval to introduce competing versions of the same drug on the market. The first and most familiar route is for a competitor to file an Abbreviated New Drug Application (ANDA) to market a generic version of the existing drug. *See Celgene*, 17 F.4th at 1117; 21 U.S.C. § 355(j). The second route accommodates potential competitors that seek FDA approval to market a drug product containing the same active moiety as an existing drug, such as by seeking approval for "a new indication or new dosage form." *FTC v. AbbVie Inc.*, 976 F.3d 327, 339 (3d Cir. 2020) (quoting 21 C.F.R. § 314.54(a)); *see* 21 U.S.C. § 355(b)(2). This case implicates this latter form of application, known as a "505(b)(2) NDA," *Antares Pharma, Inc. v. Medac Pharma Inc.*, 771 F.3d 1354, 1356 (Fed. Cir. 2014), or a "hybrid NDA," *AbbVie*, 976 F.3d at 339. These processes for expedited approval of new forms of existing drugs are designed to "promote competition in the pharmaceutical industry." *Id.*

The timing of FDA approval for an ANDA or 505(b)(2) NDA "depends on the scope and duration of the patents covering the brand-name drug." *Caraco Pharm. Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). To

"facilitate the approval of [new] drugs as soon as patents allow," the Hatch-Waxman Act "direct[s] brand manufacturers to file information about their patents" with the FDA. *Id.* As originally enacted, the Act provided that an NDA applicant "shall file with the application the patent number and the expiration date of any patent which *claims the drug* for which the applicant submitted the application or which *claims a method of using such drug*." Pub. L. No. 98-417, § 102, 98 Stat. 1585, 1592 (1984) (emphasis added); *see also* 21 U.S.C. § 355(b)(1) (1988). Thus, as has always been the case, the Act directs brand-name NDA holders to submit patent information for two "different varieties" of patent. *Caraco*, 566 U.S. at 405. The first protects "the drug compound itself." *Id.* The other protects "a particular method of using the drug." *Id.*

Pursuant to this statutory scheme, the FDA requires NDA holders to submit patent information on any "drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents" that claim "the drug or a method of using the drug that is the subject of the NDA," 21 C.F.R. § 314.53(b)(1), both before and after the NDA is approved. As to method-of-use patents, once an NDA is approved, the applicant must submit a "description of the patented method of use," *id.* § 314.53(c)(2)(ii)(P)(3), known as a "use code." *Caraco*, 566 U.S. at 405. "[T]he FDA does not attempt to verify the accuracy of the use codes that brand manufacturers supply. It simply publishes the codes, along with

the corresponding patent numbers and expiration dates, in a fat, brightly hued volume called the Orange Book (less colorfully but more officially denominated Approved Drug Products With Therapeutic Equivalence Evaluations)." *Id.* at 405-06.

Publication of a patent in the Orange Book is highly significant for prospective ANDA or 505(b)(2) NDA applicants. If an ANDA or 505(b)(2) NDA applicant seeks FDA approval to market a drug for which there is an active Orange Book patent listing before expiration of that patent or any related term of exclusivity, the applicant may file a "Paragraph IV certification" that the patent is invalid or that the applicant's product will not infringe it. 21 U.S.C. § 355(b)(2)(A)(iv), (j)(2)(A)(vii)(IV). A Paragraph IV certification constitutes an act of statutory infringement of the relevant patent, giving the patent holder an "immediate right to sue." *Caraco*, 566 U.S. at 407 (citing 35 U.S.C. § 271(e)(2)(A)). If the patent holder sues within 45 days, it receives an automatic 30-month regulatory stay during which the FDA cannot approve the competitor's ANDA or 505(b)(2) NDA application. *See* 21 U.S.C. § 355(c)(3)(C), (j)(5)(B)(iii).

As the FDA's manner of publishing use codes in the Orange Book suggests, the FDA's "duties with respect to Orange Book listings are purely ministerial." *Apotex*, 347 F.3d at 1348. That is, the FDA has no duty—and does not consider itself qualified—to "screen Orange Book submissions by NDA applicants and to

refuse to list those [patents] that do not satisfy the statutory requirements for listing." *Id.* at 1349. Rather, the FDA takes the position that "it is the responsibility of the NDA holder to determine whether a patent claims the drug or a method of using the drug that is the subject of the NDA for purposes of Orange Book listing," and that the FDA's "sole responsibility" with respect to the Orange Book is to "publish" the information that the NDA applicant submits. *Id.* at 1347.

Indeed, in its very first rulemaking addressing its statutory obligations with respect to the Orange Book, the FDA rebuffed calls to review the patent information submitted for listing in the Orange Book. As the FDA explained, it has neither "the expertise [n]or the desire to become involved in issues concerning patent law." 59 Fed. Reg. 50338, 50350 (Oct. 3, 1994). Because it "does not have the expertise to review patent information," it determined that "its scarce resources would be better utilized in reviewing applications rather than reviewing patent claims." *Id.* at 50343.

The FDA reiterated that position in 2003, when it adopted additional regulations governing Orange Book listing. *See* 68 Fed. Reg. 36676 (June 18, 2003). As the FDA explained, "[a] fundamental assumption" of the Hatch-Waxman Act "is that the courts are the appropriate mechanism for the resolution of disputes about the scope and validity of patents. The courts have the experience, expertise, and authority to address complex and important issues of patent law." *Id.* at 36683.

2. Orange Book Delisting—The *Apotex* Case And Congress's Creation Of A Statutory Counterclaim

The FDA's ministerial view of its role in publishing Orange Book listings led to frustration among drug makers who believed that certain patent information was improperly listed in the Orange Book. As the Supreme Court later summarized, "In the late 1990's, evidence mounted that some brands were exploiting this statutory scheme to prevent or delay the marketing of generic drugs" by submitting "inaccurate patent information to the FDA." *Caraco*, 566 U.S. at 408.

Generic drug manufacturers first sought relief in the courts. In 2001, a generic drug maker (Apotex) sued the FDA under the Administrative Procedure Act, arguing that the FDA had improperly listed certain "recently issued [SmithKline] patents" that did not claim an "approved new drug or a method of using that drug." *Apotex*, 347 F.3d at 1343. The district court granted the FDA's motion to dismiss Apotex's delisting claim on the ground that "there is no cause of action against the FDA to de-list a patent from the Orange Book." *Id.* at 1341.

Apotex appealed to this Court, which first reviewed its jurisdiction over Apotex's novel "de-listing claim." *Id.* at 1343. As this Court noted, the "Administrative Procedure Act is clearly not an act of Congress 'relating to patents,'" so the question whether this Court had jurisdiction over Apotex's APA claim against the FDA turned on "whether Apotex's right to relief necessarily depends on resolution of a substantial question of federal patent law." *Id.* (citing

Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 808 (1988)). This Court held that Apotex's claim *did* turn on resolution of a substantial question of federal patent law, as identified in the Orange Book listing statute: "[I]n order to obtain relief on its claim against the FDA, Apotex would have to establish that one or more of the patents that SmithKline submitted for listing in the Orange Book claims neither the drug that is the subject of SmithKline's 1992 NDA nor a method of using that drug." *Id.* at 1344. This Court reasoned that "[b]oth of those questions are issues of patent law." *Id.* In other words, Apotex's claim called for a determination whether "the claims of those patents read on the approved drug or if a claim of patent infringement could reasonably be asserted with respect to the *method claims* of those patents." *Id.* (emphasis added).

On the merits, however, this Court agreed with the district court: Apotex had no statutory right to demand that the FDA delist the SmithKline patents from the Orange Book. The *Apotex* Court determined that "nothing in the Hatch-Waxman Act" suggests "that the FDA has a duty to screen Orange Book submissions by NDA applicants and to refuse to list those that do not satisfy the statutory requirements for listing," and so it upheld as "reasonable" the FDA's conclusion that "the Act does not require [the FDA] to police the listing process by analyzing whether the patents listed by NDA applicants actually claim the subject drugs or applicable methods of using those drugs." *Id.* at 1349. It therefore rejected Apotex's argument that

"pursuant to the dictates of the Hatch-Waxman Act, the district court should have ordered the FDA to review the contents of the [listed] patents and to remove from the Orange Book any of those patents that do not comply with the statutory listing requirements." *Id.*

Judge Plager wrote a concurring opinion noting his "[r]eluctant[]" agreement with the conclusion that "the statute does not explicitly place a duty on the FDA" to police Orange Book listings. *Id.* at 1352. But Judge Plager noted that this conclusion was "at odds with [his] notion of proper administration of the law," since a "listing in the Orange Book" carries "significant legal consequences," and there should be "a neutral arbiter" to decide this "important matter of process." *Id.* at 1352-53. He therefore urged that if "neither the Administration nor the courts see fit … to administer the [Hatch-Waxman] Act in a responsible way, Congress should consider doing so." *Id.* at 1354.

Congress took up Judge Plager's suggestion almost immediately. In December 2003—months after this Court handed down its decision in *Apotex*—Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. *See* Pub. L. No. 108-173, 117 Stat. 2066. In that legislation, Congress amended the Hatch-Waxman regime by providing a statutory remedy for drug makers like Apotex that sought the delisting of certain patents listed in the Orange Book. Specifically, Congress provided that, where a patent holder "brings a patent

infringement action" against an ANDA or 505(b)(2) NDA applicant, "the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by" the patent holder to the FDA for inclusion in the Orange Book "on the ground that the patent does not claim either—(aa) the drug for which the application was approved; or (bb) an approved method of using the drug." *Id.* § 1101(b)(2), 117 Stat. at 2452; 21 U.S.C. § 355(c)(3)(D)(ii)(I).

Thus, Congress "responded" to Orange Book listing "abuses," *Caraco*, 566 U.S. at 408, by enabling ANDA and 505(b)(2) NDA applicants (such as Avadel), which had been made defendants in infringement actions involving a patent listed in the Orange Book, to challenge that listing via the new statutory delisting counterclaim. This new delisting provision satisfied the need for some "neutral arbiter"—an Article III court—to determine whether the listed patent belonged in the Orange Book. *Apotex*, 347 F.3d at 1353 (Plager, J., concurring). And it offered the prospect of immediate "judicial vindication" of an ANDA or 505(b)(2) NDA applicant's legal position vis-à-vis that Orange Book listing, so as to minimize the negative consequences stemming from the statutory 30-month stay. *Id.* Moreover, by channeling review of the delisting criteria to Article III courts, Congress's solution kept those "issues of patent law" where this Court and the FDA agreed they belonged. *Apotex*, 347 F.3d at 1344; *see also* 68 Fed. Reg. 36683.

3. The Orange Book Transparency Act of 2020

Most recently, Congress passed the Orange Book Transparency Act of 2020, formally enacted on January 5, 2021. Pub. L. No. 116-290, 134 Stat. 4889 (2020). That enactment did not alter the text of the delisting counterclaim set out at 21 U.S.C. § 355(c)(3)(D)(ii)(I). Rather, the OBTA sought to close the door on abusive listings of "drug" patents in the Orange Book by specifying that a patent that claims a "drug for which the applicant submitted the application" must be a "drug substance (active ingredient) patent or a drug product (formulation or composition) patent." *Compare* Pub. L. No. 116-290, § 2(a)(1), 134 Stat. at 4889, *with* 21 U.S.C. § 355(b)(1) (2018). And, as amended by the OBTA, an NDA applicant must continue to list any patent that "claims a method of using such drug for which approval is sought or has been granted in the application." 134 Stat. at 4889.

B. Sodium Oxybate, Xyrem, And Jazz's '963 Patent

Jazz holds an FDA-approved NDA for Xyrem®, a sodium oxybate oral solution used to treat the symptoms of the sleep disorder narcolepsy, including cataplexy. Sodium oxybate is "older than aspirin," and has been used to treat narcolepsy since the 1960s; the compound itself is no longer covered by any active patents. *See In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829, 833-37 (N.D. Cal. 2021). The NDA for Xyrem was approved in 2002. Jazz did not develop Xyrem; it acquired Xyrem in 2005 when it purchased another drug maker.

See id. at 837. Since then, Jazz has obtained multiple patents relating to Xyrem's use and distribution. Xyrem remains an expensive and lucrative brand drug today, over 20 years after its introduction. Jazz enjoys revenues of over $1.3 billion per year on sales of Xyrem. *See* Jazz Pharmaceuticals, Inc., Annual Report (Form 10-K) at 7 (Mar. 1, 2022), https://investor.jazzpharma.com/node/18996/html. In 2020, Medicare Part D alone spent an average of $14,360 per prescription and $138,116 per beneficiary on Xyrem, for a total cost to Medicare of over $287 million. *See* Medicare Part D Drug Spending, https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug (open Dataset for Medicare Part D Spending by Drug – Excel Reports including Historical Data) (last accessed Jan. 11, 2023).

Sodium oxybate is a form of gamma-hydroxybutyrate (GHB), which is subject to abuse and misuse and is thus a Schedule III controlled substance. *See* 21 C.F.R. § 1308.13(c)(6). Because of this, the FDA requires that sodium oxybate products be distributed in accordance with a Risk Evaluation and Mitigation Strategy (REMS). The Xyrem REMS—proposed by Jazz, then approved by the FDA—requires that Xyrem be distributed only to patients with a valid prescription, and contains procedures to ensure that Xyrem is not distributed to others, principally by mandating that "all Xyrem and Xyrem generics" be dispensed "through a single centralized pharmacy." *Xyrem*, 555 F. Supp. 3d at 841.

Jazz's Xyrem REMS is a source of controversy, including an ongoing multidistrict litigation in the Northern District of California concerning allegations that "Jazz abused the FDA's REMS process." *Id.* Even though the FDA approved Jazz's REMS proposal, the FDA itself "criticized Jazz's 'repeated, lengthy delays' and Jazz's inconsistent position on whether 'a single pharmacy is critical to the safe use of Xyrem.'" *Id.* at 842 (quoting Letter from Billy Dunn, FDA Director of Neurology Products, to Jazz Pharmaceuticals at 3 (Feb. 27, 2015), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021196Orig1s015ltr.pdf).

The FDA has expressed doubt as to both "(1) the objective merits of Jazz's REMS; and (2) Jazz's subjective motivations in proposing a single-pharmacy REMS," *id.*, noting that Jazz's shifting REMS proposals suggested that Jazz crafted its eventual single-pharmacy REMS proposal with the "knowledge" that it "could have the effect of preventing generic competition," *id.* (quoting Memorandum from Trueman Sharp, Deputy Director for the FDA Office of Generic Drugs, to ANDAs for sodium oxybate oral solution products, at 26 (Jan. 17, 2017) ("Sharp Memo"), https://www.fda.gov/media/102913/download). In light of these concerns, after approving Jazz's proposed REMS, the FDA "waived the single-pharmacy [REMS] requirement for generic versions of Xyrem," *id.*, concluding that "allowing ANDA applicants to proceed with their own drug distribution systems would 'remove a barrier to generic products coming to market,'" *id.* at 843 (quoting Sharp Memo 17).

This Court is no stranger to Jazz's '963 patent, which is part of a "family of patents owned by Jazz relating to a drug distribution system for tracking prescriptions" of Xyrem, pursuant to Xyrem's REMS. *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347, 1350 (Fed. Cir. 2018). Many claims in that patent family, including several of the '963 patent claims, were found unpatentable as obvious by the Patent Trial and Appeal Board in *inter partes* review—and this Court affirmed. *Id.* at 1363.

Jazz acknowledges that the '963 patent claims "a computer-implemented system to safely distribute sodium oxybate for treatment of a narcoleptic patient." OB15. "Specifically, the independent claims recite a 'computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion ….'" *Id.* (alteration in original) (quoting Appx98 (8:39-41)). Even so, Jazz listed the '963 patent in the Orange Book, and Jazz's use code describes the '963 patent as claiming a "*method* of *treating* a patient with a prescription drug using a computer database in a computer system for distribution." Appx3978 (emphasis added).

C. Avadel's 505(b)(2) NDA For LUMRYZ™

Avadel has spent many years and hundreds of millions of dollars developing a novel drug called LUMRYZ™ (also known as FT218), which allows narcolepsy patients to take a single dose of sodium oxybate at bedtime to help them fall asleep

and stay asleep throughout the night. Appx3968-3976. Avadel's once-nightly sodium oxybate formulation reflects a significant advancement in the treatment of the symptoms of narcolepsy. In contrast, Jazz's Xyrem requires patients to take *two* nightly doses (a first dose at bedtime and then, after being forcibly awakened two to four hours later, another dose in the middle of the night). Currently, many narcolepsy patients forgo treatment with sodium oxybate because they cannot comply with this disruptive dosing regimen. Appx4070-4071. The novel formulation and dosing regimen of LUMRYZ will allow narcolepsy patients to obtain a full night's sleep without interruption.

In December 2020, Avadel filed a 505(b)(2) NDA for LUMRYZ. *See supra* at 7 (describing 505(b)(2) NDAs). In connection with that application, Avadel proposed a LUMRYZ REMS that would use multiple pharmacies and four separate, distinct databases to ensure the drug is dispensed only to patients with a valid prescription. Because the LUMRYZ REMS does not use a single, centralized database, Avadel took the position that Jazz's '963 patent—which claims a computer system to support a centralized, single-pharmacy REMS—was inapplicable. Avadel filed a statement to this effect with the FDA pursuant to 21 U.S.C. § 355(b)(2)(B), rather than a Paragraph IV certification. Appx3978-3979.

Without making any determination as to infringement, the propriety of the '963 patent's listing in the Orange Book, or the accuracy of the use code supplied

by Jazz for that listing, the FDA required Avadel to convert its statement to a Paragraph IV certification, or otherwise wait until the patent expired, to market LUMRYZ. Appx3977-3993. Avadel complied by submitting a Paragraph IV certification, thereby giving Jazz a statutory cause of action for patent infringement. *See* 35 U.S.C. § 271(e)(2)(A). Following Avadel's Paragraph IV certification, Jazz promptly sued Avadel for infringement, automatically staying final FDA approval of Avadel's 505(b)(2) NDA. *See* 21 U.S.C. § 355(c)(3)(C). Although the term of the '963 patent expired on December 17, 2022, it is considered extended by six months—until June 17, 2023—for FDA approval purposes on account of Jazz's pediatric exclusivity. *See id.* § 355a(b)(1)(B). The FDA granted tentative approval to LUMRYZ on July 18, 2022. Appx3665-3681. The '963 patent is the only Orange Book-listed patent that Jazz has asserted against Avadel, and which forms the basis for the statutory stay of final approval.

D. District Court Proceedings and Decisions

Jazz filed its initial complaint against Avadel in the district court in May 2021. Appx51. In its June 2021 answer, Avadel filed a counterclaim seeking to delist the '963 patent on the grounds that the '963 patent claims a "computer-implemented system," and does not claim either "a drug product or drug substance" or "a method of using [an] approved drug product." Appx461-462.

Avadel quickly moved for judgment on the pleadings on its delisting counterclaim pursuant to Rule 12(c). Appx521. Jazz opposed that motion, arguing that it required the district court to "construe the claims" of the '963 patent, Appx841, and that "[c]laim construction determinations cannot be made at the pleadings stage," Appx845. Jazz argued that, although the claims' preambles described a "computer-implemented system" and the claims' elements were "computer memories" and a "data processor," (Appx98-100) the claims nonetheless "recite methods." Appx842-843. Jazz also argued that FDA regulations required, or at least permitted, Jazz to list the '963 patent in the Orange Book in the first instance. Appx839. The district court agreed with Jazz that Avadel's motion for judgment on the pleadings "depend[ed] in no small part on claim construction and the question of whether the claimed 'system' includes methods of using the approved product." Appx1449. It denied Avadel's motion and proceeded to order claim-construction briefing, in which the parties disputed whether the '963 patent claims a system (Avadel's position) or methods (Jazz's position). In particular, Jazz asserted that the claims set out in the '963 patent "are, in fact, method claims because the body of the claims require the performance of particular method steps." Appx2873-2874 (quoting *Lyda v. CBS Corp.*, 838 F.3d 1331, 1339 (Fed. Cir. 2016)).

On June 23, 2022, after the parties exchanged claim-construction briefs, Avadel renewed its Rule 12(c) motion regarding delisting of the '963 patent.

Appx2478. Jazz opposed Avadel's renewed motion on the same two grounds it raised in its initial opposition. First, Jazz reiterated that the '963 patent "claims cover methods of using a computer-implemented system," and rested on its "*Markman* [claim-construction] briefing" for that position. Appx3606. Second, Jazz asserted that, even if the district court determined that the '963 patent claimed only systems rather than methods, delisting would be inappropriate because "Jazz was permitted to list the '963 patent in the Orange Book under the statute and regulations that were applicable at the time of its listing." Appx3615-3617. Jazz also contended (for the first time) that application of the delisting statute would require retroactive application of the Orange Book Transparency Act. Appx3615-3617; *see* Appx3603.

Importantly, Jazz *never argued*—in either of its Rule 12(c) oppositions—that, if the district court construed the '963 patent claims as systems, such claims could be understood to cover a method of using a drug under the delisting statute itself. That is, Jazz never argued that the statutory delisting provision's reference to a patented "*method* of using the drug" (21 U.S.C. § 355(c)(3)(D)(ii)(I)(bb) (emphasis added)) means anything other than in the sense contemplated by patent-law principles, nor that a "method" should be interpreted to include patented *systems*. *See* Appx828-849; Appx3597-3621; Appx5674-5686.

The FTC filed an amicus brief urging the district court to order delisting "to the extent Jazz's '963 patent claims a REMS distribution system rather than a

method of using Xyrem." Appx5672; *see* Appx5647-5673. The FTC took no position on the parties' claim-construction arguments, although it noted that "*[e]ven a method patent* … fails to meet Orange Book listing criteria if it covers a method of distributing—as opposed to using—a drug." Appx5663 n.17 (emphasis added). The FTC explained, however, that "[t]o the extent the '963 patent is directed to the implementation of a REMS distribution system, it plainly does not cover 'a drug,'" and a "REMS distribution system cannot plausibly be considered a 'method of using a drug.'" Appx5667. Thus, if "the Court determines that the '963 patent covers only a REMS distribution system … the Court should order Jazz to delist it." Appx5672.

The district court agreed with Avadel and the FTC. On November 18, 2022, in successive opinions, the district court issued a *Markman* order agreeing with Avadel's construction of the '963 claims (Appx5707-5731) and an order granting judgment to Avadel on its delisting counterclaim (Appx1-9). As the district court explained in its *Markman* order, "the claims of the '963 patent are directed to systems, not methods." Appx5725. This "claimed system is an assemblage of [computer] components that together operate to accomplish the prescribed purpose," Appx5723, namely, to "safely distribute gamma-hydoxybutyrate," Appx5722.

The district court's order granting judgment on Avadel's delisting counterclaim followed naturally from its *Markman* order. As the district court explained, Section 355(c)(3)(D)(ii)(I) requires delisting where the patent at issue

"does not claim either—(aa) the drug for which the application was approved; or (bb) an approved method of using the drug." Appx6 (quoting 21 U.S.C. § 355(c)(3)(D)(ii)(I)). "The parties do not dispute that the '963 patent does not claim a drug." Appx7. And, relying on its *Markman* order, the district court further reasoned that "the '963 patent does not claim 'an approved method of using the drug' because the claims of [the] '963 patent are directed to systems, not methods." Appx7. Because Jazz had "advance[d] no theory that the '963 patent, *construed as claiming systems*, could constitute 'an approved *method* of using the drug'" under the delisting statute, the court recognized that its "construction of the '963 patent disposes of the inquiry." Appx7 (emphasis added).

Next, the district court addressed the only contrary arguments that Jazz raised: namely, that Jazz was originally "'permitted' to list the '963 patent in the Orange Book," and that granting Avadel's delisting motion would involve the "retroactive[]" application of the OBTA. Appx8. The district court properly rejected these arguments based on the plain language of the delisting statute.

As the court explained, "[T]he delisting statute does not require inquiring as to whether the [patent] holder was authorized to list the patent in the first instance." Appx8. It simply "states that patents that do not claim either a drug or method of using a drug may be either 'correct[ed] or delete[d]'" from the Orange Book. Appx8 (alterations in original). Thus, the assertion that Jazz was originally permitted to list

the '963 patent was "not relevant." Appx8. Relatedly, "the delisting statute, 21 U.S.C. § 355(c)(3)(D)(ii)(I), afford[s] Avadel a present right to seek delisting under the identified conditions." Appx7. And the delisting statute "was enacted in 2003—long before Jazz submitted the '963 patent for listing in the Orange Book in 2014." Appx8. Jazz's retroactivity argument was "not relevant" insofar as it rested on a provision of the OBTA, 21 U.S.C. § 355(c)(2), a "provision [that] on its face does not impact an applicant's right to a delisting counterclaim under 21 U.S.C. § 355(c)(3)(D)(ii)(I)." Appx7-8.

Having disposed of Jazz's arguments by reference to the plain language of the governing statute and the claim construction that Jazz had insisted was necessary, the district court granted Avadel's renewed motion for judgment. Appx9. It therefore enjoined "Jazz to correct or delete the patent information submitted by Jazz in the Orange Book" within 14 days. Appx9 (citing 31 C.F.R. § 314.53(f)(2)(i)).

Jazz filed a notice of appeal and moved the district court and this Court to stay the injunction pending appeal. *See* ECF Nos. 1, 5. In those motions, Jazz's principal argument—which it had never raised before—was that as a matter of plain language the statutory delisting provision's reference to "methods" includes "systems," without reference to "patent law definitions." Appx5745-5771 at Appx5760; *see* ECF No. 5 at 13-15. On November 29, 2022, this Court issued a temporary stay pending resolution of the concurrent district court motion. ECF No. 10.

On December 5, 2022, the district court denied Jazz's stay motion, emphasizing that Jazz had "forfeited" its principal merits argument. Appx6348-6352 at Appx6350. On December 14, 2022, this Court determined that, "in light of the scheduled February [2023] hearing for this expedited appeal, and without prejudicing the ultimate disposition of this case by a merits panel, … the better course is to extend this court's stay of the district court's order until further notice." ECF No. 28 at 2.

SUMMARY OF ARGUMENT

I.A. As a matter of plain statutory text, the district court's decision was correct. The delisting statute provides a counterclaim for delisting an Orange Book-listed patent unless the patent "claims" either (aa) an approved "drug" or (bb) "an approved method of using the drug." 28 U.S.C. § 355(c)(3)(D)(ii)(I). As this Court has recognized, these are "issues of patent law." *Apotex*, 347 F.3d at 1344. The district court therefore correctly analyzed the claims of the '963 patent by reference to principles of patent claim construction, and determined that the '963 patent does not claim either a "drug" or an "approved method of using [a] drug." Appx7. Indeed, as the district court found, the '963 patent does not claim any "methods" at all, but rather claims "systems." Appx7. That claim-construction analysis "disposes of the [delisting] inquiry." Appx7.

I.B. Jazz's insistence that patent law does not govern this case, and that its '963 patent claims—despite reciting a "system"—nonetheless qualify as "method[s] of using [a] drug" in ordinary English parlance, fails three times over. First, it fails because it is forfeited: Jazz never argued in district court that patent law does not govern the delisting inquiry, and it never advanced the plain-meaning argument it advances here. Second, it fails on the merits: When Congress directed courts to examine what a "patent" does or does not "claim," it clearly imported patent-law terms and directed courts to examine patent claims according to ordinary claim-construction principles. Third, Jazz's argument fails on its own terms: Under the plain language of the statute, the '963 patent does not claim a method of "*using*" a drug; it describes a computer system for *distributing* a drug.

II. Jazz next argues that Avadel's delisting counterclaim depends on showing that the '963 patent was not properly listed in the first place. The district court properly rejected that argument. The delisting statute—which was enacted in 2003 (over a decade before Jazz listed the '963 patent), and which has not changed—does not depend on historical analysis.

And, in any event, the '963 patent was *not* properly listed in the first place. The statutory criteria for Orange Book listing were not materially different in 2014—when the '963 patent was listed—than they are today, and they are not materially different from the statutory delisting criteria governing this case. Jazz's appeal to

FDA regulations is mistaken, as those regulations do not permit listing of the '963 patent and could not, in any event, possibly trump plain statutory language providing for the listing of patents that claim *drugs* or *methods of using drugs*. The FDA has consistently maintained that it is not expert in patent law and plays only a ministerial role in the listing process; Jazz's effort to make FDA regulations the final word on the propriety of Orange Book delisting is backward. And Jazz's continued insistence that Avadel's delisting counterclaim somehow relies on a retroactive application of the OBTA is simply mistaken: The OBTA did not amend the delisting statute.

III. Jazz saves for last the question that ought to be first: whether the district court correctly construed the '963 patent claims as systems rather than methods. Jazz's reluctance to confront the district court's analysis is understandable; Jazz's argument that the '963 patent claims methods is not tenable. On its face, every single claim of the '963 patent recites a "computer-implemented system" with computer components: "computer memories" and a "data processor." Appx98-100. These claims are drawn to computer systems, not *methods of using* computer systems, much less methods of using *a drug*. Jazz's contrary arguments here fail for the same reason they failed in the district court. Claim construction of the '963 patent disposes of the question whether the '963 patent claims a method of using a drug. Because the '963 patent does not claim methods of any kind, it should be delisted.

The district court's injunction should be affirmed, and this Court should lift its stay of that injunction.

ARGUMENT

I. THE DISTRICT COURT CORRECTLY APPLIED PATENT LAW IN EVALUATING WHAT THE '963 PATENT CLAIMS

A. The Orange Book Delisting Statute Calls For Patent-Law Claim Construction

The Orange Book delisting statute is clear: A counterclaimant asserting a delisting claim is entitled to relief if it can show that the listed patent "does not claim either—(aa) the drug for which the application was approved; or (bb) an approved method of using the drug." 21 U.S.C. § 355(c)(3)(D)(ii)(I). The statute calls for *claim construction* of the listed "patent" to determine what the patent "claim[s]" as a matter of *patent law*. That conclusion is mandated not only by the language of the delisting statute, but also by statutory context, and by precedent in this Court and the Supreme Court indicating that the inquiries at issue here present "issues of patent law." *Apotex*, 347 F.3d at 1344. Accordingly, the district court correctly resolved Avadel's delisting counterclaim by subjecting the '963 patent to ordinary claim construction and concluding that the '963 does not claim either a "drug" or a "method" of using a drug.

1. As a matter of text, the delisting statute calls for district courts to undertake patent claim construction according to routine patent-law principles. *See*

Caraco, 566 U.S. at 412 (noting that all statutory-construction inquires "must begin" with "the language of the statute itself" (quoting *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989))). In the Orange Book delisting statute, Congress directed that 505(b)(2) NDA applicants like Avadel "may assert a counterclaim seeking an order requiring [a patent] holder to correct or delete the *patent* information submitted by the holder … on the ground that the *patent* does not *claim* either—(aa) the drug for which the application was approved; or (bb) an approved *method* of using the drug." 21 U.S.C. § 355(c)(3)(D)(ii)(I) (emphasis added).

The delisting statute presents questions about what a "patent" does or does not "claim." That language plainly invokes substantive patent law. As the Supreme Court has recently and repeatedly explained, "When a statutory term is 'obviously transplanted from another legal source, it brings the old soil with it." *Taggart v. Lorenzen*, 139 S. Ct. 1795, 1801 (2019) (quoting *Hall v. Hall*, 138 S. Ct. 1118, 1128 (2018)); *see also, e.g.*, *Stokeling v. United States*, 139 S. Ct. 544, 551 (2019). "The point of the old-soil principle is that 'when Congress employs a term of art,' that usage itself suffices to 'adopt the cluster of ideas that were attached to each borrowed word' in the absence of indication to the contrary." *George v. McDonough*, 142 S. Ct. 1953, 1963 (2022) (quoting *FAA v. Cooper*, 566 U.S. 284, 292 (2012)). Thus, for example, where the Bankruptcy Code specifies that "a discharge order 'operates as an injunction,' [11 U.S.C.] § 524(a)(2), and that a court may issue any 'order' or

'judgment' that is 'necessary or appropriate' to 'carry out' other bankruptcy provisions, [11 U.S.C.] § 105(a)," those words "bring with them the 'old soil' that has long governed how courts enforce injunctions." *Taggart*, 139 S. Ct. at 1801.

So too here: The delisting statute's inquiry into what a "patent" does not "claim" is clearly imported from patent law and brings with it the old soil of patent-law principles that courts use in construing patent claims. As the Supreme Court and this Court have held, "a patent claim" is a phrase with a distinct meaning: "that 'portion of the patent document that defines the scope of the patentee's rights.'" *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321 (2015) ("*Sandoz*") (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (2015)); *see Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970 (Fed. Cir. 1995) (patent claims "define the scope of the patentee's rights under the patent"). The "construction of patent claims" is "a matter of law exclusively for the court," *Markman*, 52 F.3d at 970-71, and is carried out according to a rich body of interpretive legal principles, *see Sandoz*, 574 U.S. at 331 (noting that the Supreme Court "has repeatedly compared patent claim construction to the construction of other written instruments such as deeds and contracts").

Thus, when Congress directed courts to consider what a "patent does not claim," 21 U.S.C. § 355(c)(3)(D)(ii)(I), it "adopt[ed] the cluster" of claim-construction "ideas" attached to that inquiry. *George*, 142 S. Ct. at 1963 (quoting

Cooper, 566 U.S. at 292). Among them is the idea that a "method" claim, as referenced in the delisting statute, has a certain meaning in patent law, carrying certain interpretive consequences. *See, e.g.*, *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014) ("A method patent claims a number of steps; under this Court's case law, the patent is not infringed unless all the steps are carried out."); *LifeNet Health v. LifeCell Corp.*, 837 F.3d 1316, 1325 (Fed. Cir. 2016) ("Direct infringement of a method claim requires all steps of the claimed method to be performed by or attributable to a single entity."). The Orange Book delisting statute, having imported the "old soil" of patent law, incorporates those understandings by reference.

2. Statutory context buttresses that conclusion. *See Caraco*, 566 U.S. at 412 (noting that statutory interpretation should focus on "the language itself, the specific context in which that language is used, and the broader context of the statute as a whole" (quoting *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997))). The statutory counterclaim created by the Orange Book delisting statute does not arise in a vacuum. Rather, Congress specifically established the delisting counterclaim as a cause of action that arising only in the context of a "patent infringement action," 21 U.S.C. § 355(c)(3)(D)(ii)(I), and not in "any" other "civil action or proceeding," *id.* § 355(c)(3)(D)(ii)(II). Thus, the statutory delisting counterclaim established by Congress *necessarily* arises in a proceeding that patent law already governs.

In any such action, the Orange Book-listed patent will underlie the patent holder's claim against the defendant—as it does here with respect to Jazz's infringement claim against Avadel. Appx58 (listing the '963 patent as a patent-in-suit). It would be incongruous if the claims embodied in an Orange Book-listed patent were construed according to patent-law principles for purposes of the patent holder's "infringement action" against a 505(b)(2) NDA applicant, but the defendant's delisting counterclaim concerning the propriety of that patent's listing in the Orange Book—a counterclaim that turns on what a patent "claims"—were construed *without reference to* those same claim-construction principles.

Congress intended that the patent's "claims" would be parsed according to the same claim-construction principles both with respect to the patent holder's infringement claims and the defendant's delisting counterclaim. Thus, for example, where a patentee presses an infringement claim resting on a patent containing "method" claims, those method claims should be construed according to ordinary patent-construction principles governing method claims, as well as the patent-law principles governing infringement claims arising from method patents. *See, e.g.*, *Limelight Networks*, 572 U.S. at 921. Likewise, a court tasked with examining a patent-in-suit that allegedly "does not claim" either a "drug" or a "method" of using a drug should do so according to the same principles of claim construction—including by giving the statutory term "method" its standard patent-law meaning.

3. Binding decisions of the Supreme Court and this Court confirm the foregoing. In *Apotex*, just before Congress enacted the delisting statute, this Court addressed a novel delisting claim resting on a patent's failure to satisfy the Orange Book *listing* criteria, and squarely held that such a delisting claim, asserting that an Orange Book-listed patent "claims neither [a] drug … nor a method of using that drug," presents "issues of patent law." 347 F.3d at 1344. Not only that, but the *Apotex* Court specifically recognized that whether a set of patents claim a "method of using [a] drug" requires inquiry into the "*method claims* of those patents." *Id.* (emphasis added). That was the basis of this Court's conclusion that an appeal concerning a delisting claim was properly within the appellate jurisdiction of this Court. Despite ultimately concluding that the claim lacked a statutory basis (which then gave rise to Congress's enactment of the delisting statute), the *Apotex* Court recognized that jurisdiction was proper because vindication of the claimant's position required "resolution of a substantial question of federal patent law," notwithstanding that the cause of action giving rise to that delisting claim originated (at the time of that case) from a source other than federal patent law. *Id.*[1]

More recently, in *Caraco*, the Supreme Court made clear that an Orange Book delisting counterclaim is a patent claim that should be resolved according to the

[1] As discussed (*supra* at 11-14), Congress responded to *Apotex* by enacting the delisting statute, which confirms that Congress intended for patent-law principles to govern here. *See Morgan v. Principi*, 327 F.3d 1357, 1361 (Fed. Cir. 2003).

principles of patent law. First, the Court recognized that an Orange Book delisting counterclaim pressed by an ANDA applicant arises under an "Act of Congress relating to patents." *Caraco*, 566 U.S. at 412 n.5 (quoting 28 U.S.C. § 1338(a)). Second, the Court noted that the "case requires us to construe two statutory phrases" in the delisting statute, including the question of "when a 'patent does not claim … an approved method of using' a drug." *Id.* at 412. In analyzing that question, the Court reasoned that "a single drug may have multiple methods of use, only one or some of which *a patent covers*," and that "a company may bring a counterclaim to show that *a method of use is unpatented* because establishing that fact allows the FDA to authorize" their drug product. *Id.* at 414-15 (emphasis added).

Third, the Court explained that the Orange Book delisting statute affords relief to ANDA applicants in the form of "delet[ing] a listing from the Orange Book when the brand holds no relevant patent and correct[ing] the listing when the brand has *misdescribed the patent's scope*." *Id.* at 420 (emphasis added). Of course, as noted above, a patent's scope, or the "scope of the patentee's rights," is a matter of what the patent claims. *Sandoz*, 574 U.S. at 321 (quoting *Markman*, 517 U.S. at 372). And that requires claim construction. *See Markman*, 52 F.3d at 970-71. Fourth, the Court recognized that the delisting statute was enacted to solve the problem of "the FDA's determination that it cannot police patent claims" by "enabl[ing] courts to *resolve patent disputes* so that the FDA can fulfill its statutory duty to approve

generic drugs that do not infringe patent rights." *Caraco*, 566 U.S. at 424-25 (emphasis added). There is no reason to believe that Congress wanted courts to "resolve patent disputes" and settle "patent rights," *id.* at 425, by anything other than settled patent-law principles.

4. In view of these guideposts, the district court's analysis was entirely sound. The district court explained that the '963 patent "does not belong in the Orange Book" because the "parties do not dispute that the '963 patent does not claim a drug," and because "the '963 patent does not claim 'an approved method of using [a] drug,'" since "the claims of [the] '963 patent are directed to systems, not methods." Appx7. Furthermore, the district court noted that Jazz itself had recognized that in order to provide relief to Avadel, the court "would have to construe the ['963 patent] claims and hold that the '963 patent covers no methods at all." Appx7 n.4 (citation omitted). And because Jazz had "advance[d] no theory that the '963 patent, construed as claiming systems, could constitute 'an approved method of using the drug,'" the court's claim construction "dispose[d] of the inquiry" called for by the delisting statute. Appx7.[2] That conclusion was correct.

[2] To be sure, the district court analyzed the rest of Jazz's argument: namely, that if "the Court rules that the '963 patent claims computer systems, then Jazz was *permitted* to list it in the Orange Book." Appx3603. As the district court explained, the question whether Jazz was permitted to *list* the '963 patent was "not relevant in view of" the delisting statute, which "does not require inquiring as to whether the NDA holder was authorized to list the patent in the first instance." Appx8.

B. Jazz Is Wrong To Suggest That The District Court Erred In Resting Its Decision On Claim Construction Of The '963 Patent

In this Court, Jazz now argues that the district court's basic inquiry was mistaken: In Jazz's view, "patent law provides the wrong framework for addressing whether a patent is properly listed in FDA's Orange Book," and the district court erred by "treat[ing]" the delisting question at issue here as a "*patent-law* question." OB27. And Jazz further argues why it was supposedly required to list its '963 patent under the listing statute and FDA regulations, even if the '963 patent claims a "system" within the meaning of patent law. OB35-40.

Three independent defects plague this line of argument, each of which allows this Court to reject it in full. First, Jazz forfeited it. Second, it contradicts this Court's binding case law, which recognizes the questions here are issues of patent law. And, third, Jazz's argument fails even on its own terms: setting aside whether patent law governs here, Jazz's argument that the '963 patent belongs in the Orange Book under the plain terms of the delisting statute is wrong.

1. Jazz's Argument Is Forfeited

At the outset, Jazz has forfeited its principal line of argument. Nowhere in the district court proceedings—until its motion for stay pending appeal—did Jazz ever suggest, as it does here (at 27), that "patent law provides the wrong framework" for addressing whether the '963 patent is subject to delisting. To the contrary, Jazz insisted from the beginning that resolution of Avadel's motion for judgment on the

pleadings required "claim construction" as a matter of patent law. Appx7 (quoting Appx840-841). Indeed, Jazz convinced the district court to deny Avadel's initial delisting motion for judgment on that basis, delaying resolution for months.

When Avadel submitted a renewed delisting motion, Jazz opposed it on the basis of alternative arguments that turned on the court's construction. First, Jazz argued that, "*if the Court rules* that the '963 patent claims *methods*," Appx3602 (emphasis added), "then Jazz was *required* to list it in the Orange Book and delisting would be improper," Appx3602. Second, and alternatively, Jazz argued that "*if the Court rules* that the '963 patent claims *computer systems*," Appx3603 (emphasis added), "then Jazz was *permitted* to list it in the Orange Book," Appx3603. In other words, Jazz argued that listing was statutorily *mandated* if the claims were *methods* and *permissive* if the claims were *systems*.

Jazz expressly couched the former argument (statutorily mandated listing) as operative only "if the Court rules that the '963 patent claims methods" as a matter of patent claim construction. Appx3602. The district court rejected that claim construction, Appx5725, and Jazz now relegates it to an after-thought in Section III of its brief, *see* OB55-58.

The latter argument (permissive listing) rested on the contention that Avadel's position required retroactive application of the OBTA, and is reiterated here at Section II of Jazz's brief. *See* OB43 (arguing that "the '963 patent was permissibly

listed in 2014"); OB51 (arguing that, prior to the OBTA, the FDA "allow[ed] *permissive* listing of patents whose listing was not expressly mandated or prohibited"). The district court separately rejected that argument as well. Appx7-8.

Crucially, Jazz's opposition *never* argued (as Jazz now does in Section I of its brief, its primary argument on appeal, *see* OB32-40) that the statutory scheme mandated treating the '963 patent as a "method of using [a] drug" within the meaning of the delisting statute *or* the listing statute, irrespective of claim construction. Jazz could have argued that the district court should not interpret the statutory term "method" under established patent-law principles and should instead interpret it as including patented system claims. But Jazz never did so. Thus, the district court correctly noted that Jazz had "advance[d] no theory that the '963 patent, construed as claiming systems, could constitute 'an approved method of using the drug.'" Appx7. And the district court reiterated that point in its order denying Jazz's motion for a stay pending appeal, noting that the argument was "forfeited." Appx6350.

Jazz now insists that it preserved the argument in its original opposition to Avadel's motion for judgment on the pleadings. OB40 (citing Appx840). But this Court will search that filing in vain for any argument along the lines now presented by Jazz in Section I of its brief: that "patent law provides the wrong framework" for resolving a delisting claim, and that Avadel's motion should be resolved without reference to patent-law claim construction. OB27. Jazz never made the argument.

And, more to the point, when the parties briefed Avadel's renewed motion for judgment—giving rise to the decision on appeal here—Jazz *expressly* contended that its mandatory-listing argument applied only if the district court "rules that the '963 patent claims methods." Appx3602. Jazz invited what it now describes as error.

Jazz also argues (at 42) that this Court should overlook Jazz's forfeiture and "exercise its power" to address Jazz's newfound argument in the first instance. But a district court's determinations may not be reversed on the basis of purported (non-jurisdictional) errors that the district court had no "opportunity" to address. *Ericsson Inc. v. TCL Commc'n Tech. Holdings Ltd.*, 955 F.3d 1317, 1323 (Fed. Cir. 2020) (quoting *HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1281 (Fed. Cir. 2012)). Allowance of late-breaking arguments like these—raised for the first time in Jazz's motions for stay pending appeal—invites gamesmanship, a heightened concern here given that Jazz secured a year's delay in the district court proceedings precisely *because* it argued that patent-law claim construction was necessary.[3] This Court should reject the arguments presented in Section I of Jazz's brief as forfeited.

[3] This Court sometimes addresses "issue[s] of statutory interpretation" concerning arguments that "a party fail[ed] to make … below." *Cemex, S.A. v. United States*, 133 F.3d 897, 902 (Fed. Cir. 1998). *But see Stubblefield v. Wilkie*, 816 F. App'x 493, 496 (Fed. Cir. 2020) (affirming judgment where appellant's "statutory interpretation argument [was] waived"). Yet Jazz asks for correction of a supposed error—the district court's decision to engage in claim construction—that Jazz itself affirmatively *demanded*. Appx843. Consideration of Jazz's new argument would reward its opportunistic litigation strategy.

2. Jazz's Argument Contradicts *Apotex*

This Court could just as easily reject Jazz's main argument on the merits because it has held that the question at issue here—whether an Orange Book listing is invalid because the patent does not claim "a method of using [a] drug"—is an "issue[] of patent law," and that a delisting claim requires the "resolution of a substantial question of federal patent law." *Apotex*, 347 F.3d at 1344. Under this Court's precedent, and consistent with the text and context of the Orange Book delisting statute, the district court properly resolved Apotex's delisting counterclaim by reference to ordinary principles of patent law.

Jazz's contrary arguments contradict this Court's (and Supreme Court) case law on this question. Jazz notes, for instance, that "Orange Book listing rules" and the delisting statute are "codified in the [Food, Drug, and Cosmetic Act (FDCA)]," at title 21 of the U.S. Code, rather than at title 35 of the U.S. Code, which deals with patents. OB29. It thus suggests that the listing and delisting provisions are "FDCA-law provisions" rather than "patent-law provisions." *Id.* The Supreme Court's decision in *Caraco* says otherwise: There, the Court made clear that an Orange Book delisting counterclaim arises "under an[] Act of Congress relating to patents." 566 U.S. at 412 n.5 (quoting 28 U.S.C. § 1338(a)). And that decision accords with this Court's recognition that an Orange Book delisting claim calls for the "resolution of

a substantial question of federal patent law," no matter where the statutory cause of action for that claim resides. *Apotex*, 347 F.3d at 1344.

Elsewhere, Jazz asserts that "the agency that Congress empowered to administer Orange Book listing is not the Patent Office but FDA," and that this Court should therefore afford *Chevron* "defer[ence] to FDA's reasonable interpretation" of the listing and delisting statutes "as reflected in its regulations." OB31. But the FDA has promulgated no regulations relating to the delisting statute, which is the relevant statute here.[4] And Jazz's argument that this Court should defer to the FDA as to what a patent claims would turn the delisting statute (and the wider listing regime) on its head. As this Court and others have explained time and again, the FDA views its function with respect to Orange Book listings as "purely ministerial." *Apotex*, 347 F.3d at 1347; *see also In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 94 (2d Cir. 2017). In other words, the FDA "publish[es] submitted patent

[4] Jazz argues that FDA regulations implementing the *listing* statute prove that the listing criteria do not turn on patent-law definitions, since those regulations prohibit the listing of "[p]rocess patents," as well as "patents claiming packaging," and certain other categories of patent. 21 C.F.R. § 314.53(b)(1). In Jazz's view, the regulations mean that a "patent-law analysis (such as claim construction) would be misplaced," OB31, since in patent law "the words 'process' and 'method' mean the same thing," *id.* (citing 35 U.S.C. § 100(b)). But Jazz correctly recognizes elsewhere that FDA regulations merely prohibit the listing of "patents claiming a *manufacturing* process or packaging." OB30 (emphasis added); *accord* Appx5670 n.32; Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 Antitrust L.J. 585, 597-98 & n.66 (2003). A process of manufacturing a drug is not a method of using a drug; there is no conflict between the regulations and the patent-law meaning of "method of using a drug."

information" in the Orange Book without "review[ing] the merits of the patent information provided." *Teva Pharms.*, 548 F.3d at 106. The FDA does this because it disclaims any "expertise or … desire to become involved in issues concerning patent law," 59 Fed. Reg. at 50350, and recognizes that "the courts are the appropriate mechanism for the resolution of disputes about the scope and validity of patents," as they have the "experience, expertise, and authority to address complex and important issues of patent law," 68 Fed. Reg. at 36683.

Thus, as the Supreme Court explained in *Caraco*, the whole point of the delisting statute is to "enable[] courts to resolve patent disputes" in view of the "FDA's determination that it cannot police patent claims." 566 U.S. at 424-25. It should be no surprise, as Jazz notes, that some "FDA regulations" relating to Orange Book listing can be hard to map onto "patent-law definitions." OB31. But that is merely because the FDA has decided not to "become involved in issues concerning patent law," 59 Fed. Reg. at 50350, and to defer responsibility for patent-law determinations surrounding Orange Book listing to the courts. And as for courts' responsibility with respect to delisting claims, it is emphatically *not* to "defer to FDA's … regulations," OB31, but to follow the statutory terms set out by Congress in the delisting statute, which identify "issues of patent law" that this Court and federal district courts are well placed to resolve. *Apotex*, 347 F.3d at 1344. This Court should decide the question presented in this case on the basis of ordinary

patent principles. And under those principles, a system is not a method—as the district court held. *See* Appx5724.

3. Jazz's Argument Fails On Its Own Terms

Finally, setting aside the issue whether patent law governs this case, Jazz's contention that the '963 patent must remain in the Orange Book under the plain terms of the delisting statute fails. Jazz argues that, "in FDA's authoritative view, the phrase 'approved method of using [a] drug' includes a drug's 'conditions of use.'" OB35 (alteration in original). It jumps from that premise to the conclusion that "the '963 patent belong in the Orange Book and should not be delisted, because it claims elements of a REMS, which constitute approved 'conditions of use' for Xyrem." *Id.* More simply, Jazz argues that consumers cannot use a drug until it is distributed, so conditions of distribution are conditions of use and thus methods of use. Nonsense.

As the FTC explained in its amicus brief, Jazz's conclusion is wrong as a matter of plain statutory language. Appx5647-5673. Even assuming that the '963 patent claims a "method" in some ordinary-language sense, it does not claim a method of use. Per the FTC, a "REMS distribution system cannot plausibly be considered a 'method of using a drug,'" because REMS distribution systems concern ways of *distributing* drugs; they do not concern methods of *use*. Appx5667-5668. There is a significant difference in ordinary meaning between "[w]hen a doctor prescribes a drug to treat a patient's condition, and selects the appropriate dosage

and route of administration," versus when a person follows "safety protocols when shipping a drug from the manufacturer to a pharmacy," or maintains "databases of approved patients or authorized prescribers." Appx5668-5669. The former situation concerns methods of use; the latter does not.

Likewise, a REMS distribution system cannot properly be understood as a "condition of use" within the meaning of FDA regulations. FDA regulations make clear that "conditions of use" are conditions of administering a drug, such as a "dosage, or method or duration of administration or application, or other *condition of use* prescribed, recommended, or suggested in the labeling of such drug." 21 C.F.R. § 310.3(h)(5); *see also, e.g.*, *id.* § 522.1680(c) (itemizing "[c]onditions of use" for oxytocin in various animals, including dosage levels and indications for use); *id.* § 522.1192(e) (itemizing "[c]onditions of use" for ivermectin in various animals, including dosage levels and indications for use). As the FTC explained, a "patent on a REMS distribution system is not a patent on how a drug is taken, or for what purpose. Nor is it a patent relating to who the drug can be prescribed to. It simply covers the logistical process of disseminating the drug through the supply chain to patients who already have a prescription." Appx5670. A REMS distribution system is "a condition of FDA *approval* for certain drugs. But that does not make it a condition of the drug's *use*." Appx5670.

Finally, Jazz seeks to draw significance from the point that "when Congress enacted the REMS statute in 2007, there were already patents listed in the Orange Book" related to risk management programs. OB37. But that does not mean that those patents were exempt from delisting; and, if anything, Congress's REMS legislation cuts *against* Jazz's position, since the REMS statute specifically prohibits any NDA holder from using a REMS to "block or delay approval" of an ANDA or 505(b)(2) NDA. 21 U.S.C. § 355-1(f)(8). That shows Congress was well aware of the "potential for abuse" posed by REMS, and shared the FDA's concerns that "brand manufacturers abuse REMS to delay the entry of generics"—concerns that have been raised with respect to the Xyrem REMS itself. *Xyrem*, 555 F. Supp. 3d at 841 (internal quotation marks and citation omitted).

In short, the '963 patent does not in any sense claim a "method of using" a drug. Even if Jazz's argument were not forfeited, it would fail on its own terms.

II. THE '963 PATENT MUST BE DELISTED UNDER CURRENT LAW, AND WAS NOT PROPERLY LISTED IN THE FIRST PLACE

Next, Jazz argues that the delisting statute does not apply because FDA regulations permitted the Orange Book listing of the '963 patent in the first instance in 2014. For purposes of this argument, Jazz accepts that neither the listing statute, *see* 21 U.S.C. § 355(b)(1), nor the listing regulations, *see* 21 C.F.R. § 314.53(b)(1), actually directed the listing of the '963 patent in 2014; instead, Jazz asserts that the statute was "silent" as to patents that did not claim a drug or method of using a drug,

and that the FDA "left the door open" to listing other types of patents in the Orange Book in its regulations. OB44. Jazz raised this argument in the district court, which easily rejected it by explaining that the argument was "not relevant in view of" the delisting statute's clear language. Appx8. The district court was correct. In any event, the '963 patent was *not* properly listed in the first place.

A. The Clear Terms Of The Delisting Statute Govern Avadel's Delisting Counterclaim

Jazz contends (at 44-45) that when it submitted the '963 patent for listing in 2014 it was "permitted" to do so by FDA regulations which, in addition to identifying patents that were *required* to be listed (i.e., drug patents and patents claiming a method of using a drug), also identified four narrow categories of patents that could not be listed in the Orange Book: "[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates." 21 C.F.R. § 314.53(b)(1). Jazz asserts that, prior to the enactment of the Orange Book Transparency Act of 2020, any patent outside of those four narrow categories could permissibly be listed in the Orange Book. OB49-50. And, in Jazz's view, a permissibly listed patent cannot be delisted pursuant to the delisting statute. OB49-50. Jazz acknowledges that, under its reading, the delisting statute is inoperable with respect to any patents listed until 2021, except for "[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates." OB50 n.6 (alteration in original) (quoting 21 C.F.R. § 314.53(b)(1)).

Jazz is mistaken. From the moment that Jazz submitted its '963 patent for Orange Book listing in 2014, federal law provided for its delisting in the event that a counterclaimant could show that the patent did not claim either a drug or a method of using a drug. *See* 21 U.S.C. § 355(c)(3)(D)(ii)(I) (2012). That delisting provision was and is in harmony with the statutory *listing* provisions in force at the time, which provided for Orange Book listing of "any patent which claims the drug for which the [NDA] applicant submitted the application or which claims a method of using such drug." *Id.* § 355(b)(1) (2012). By requiring that such patents "shall" be so listed, Congress exclusively delineated those eligible for listing. *See Carcieri v. Salazar*, 555 U.S. 379, 391-92 (2009). And, consistent with the statutory listing criteria, Congress gave parties in Avadel's position a statutory right to obtain *delisting* of any patent that did not claim either a "drug" or a "method of using" a drug. 21 U.S.C. § 355(c)(3)(D)(ii)(I). Indeed, Congress did so precisely to curb the rampant "abuses" of improperly-listed patents (like the '963) keeping competing products off the market—not to enshrine them for all time. *See Caraco*, 566 U.S. at 408-09.

The question at issue here is whether Avadel is entitled to relief on its delisting counterclaim. The "clear statutory language" of the delisting statute governs that question, and that clear language "must be given effect." *Rosete v. Off. of Pers. Mgmt.*, 48 F.3d 514, 517 (Fed. Cir. 1995); *see also Rotkiske v. Klemm*, 140 S. Ct. 355, 360 (2019) ("If the words of a statute are unambiguous, this first step of the

interpretive inquiry is our last."). Congress did not provide for the delisting only of "[p]rocess patents, patents claiming packaging, patents claiming metabolites, [or] patents claiming intermediates." 21 C.F.R. § 314.53(b)(1). A court analyzing a delisting claim under that standard would have to rewrite the delisting statute in order to include those delisting criteria. This Court cannot do that. *See Langdon v. McDonough*, 1 F.4th 1008, 1011 (Fed. Cir. 2021) ("We cannot rewrite th[e] text to include criteria absent from its face.").

As to Jazz's lingering contention (at 51-54) that the district court's decision retroactively applied the OBTA, that is simply untrue for the reason provided by the district court: The OBTA did not amend or affect the operation of the delisting statute. Appx7-8. The delisting statute, enacted in 2003, "long before Jazz submitted the '963 patent for listing in the Orange Book in 2014," Appx8, controls this case, and its application does not require a retroactive application of the OBTA.

Because resolution of Avadel's delisting claim hangs on the clear terms of the delisting statute—and not the terms of FDA listing regulations, or the OBTA—the district court correctly recognized that whether the '963 patent was properly listed in 2014 pursuant to FDA regulations was "not relevant." Appx8.

B. Jazz's '963 Patent Was Not Properly Listed In The First Instance

Even if the propriety of Jazz's original '963 Orange Book listing were relevant (it is not), Jazz's argument would still fail because the '963 patent was not properly

listed. Jazz's assertion to the contrary presumes that, until the enactment of the OBTA, there was a statutory "gap" as to "what should be listed (or not listed)" in the Orange Book. OB49. But that gap is of Jazz's own conjuring: the listing statute itself was and is entirely clear in setting out what kinds of patents are be listed: patents claiming a "drug" or a "method of using" a drug. 21 U.S.C. § 355(b)(1)(A)(viii); *see In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 7-8 (1st Cir. 2020). Those criteria, which mirror the delisting statute, are similarly unambiguous and need no further interpretation. *See Rotkiske*, 140 S. Ct. at 360. As reflected by the delisting statute, those listing criteria represent the only proper bases for listing; and, under those criteria, the '963 patent was not properly listed for the same reasons it is subject to delisting.

Jazz's argument that its '963 patent was properly listed in the first instance turns entirely on (a misreading of) FDA regulations. And while Jazz once again pretends (at 49) that this Court should give *Chevron* deference to FDA regulations concerning what patents are or are not subject to Orange Book listing, that argument (again) flips the listing regime and the delisting statute on its head: Congress enacted the delisting statute precisely because the FDA plays a "purely ministerial" role in the listing process, *Apotex*, 347 F.3d at 1347, and has consciously left all patent-law inquiries in connection with that process to the courts. And deference would be unavailable here in any event: the language of the listing statute is clear and

unambiguous, and any FDA regulation construed to conflict with it would be void. *See Hyundai Steel Co. v. United States*, 19 F.4th 1346, 1354 (Fed. Cir. 2021).

Furthermore, Jazz's view of the FDA's listing regulation is unsustainable. If Jazz were right that, prior to the enactment of the OBTA, *any* patent could be properly listed in the Orange Book so long as it was not a "[p]rocess patent[], patent[] claiming packaging, patent[] claiming metabolites, [or] patent[] claiming intermediates," 21 C.F.R. § 314.53(b)(1), then a patent holder could list virtually *any* patent, including a system patent, without respect to whether it was a "drug" patent or a "method of use" patent. But Jazz itself recognized that this was not the case when it submitted the '963 patent for listing, which is why it took the trouble of crafting a (baseless) use code that made it appear as if the '963 patent claimed a method of use, i.e., "method of treating a patient." Appx3978. Jazz's use code only underscores the degree to which Jazz's misconstruction of the relevant FDA regulations in this Court is adopted purely for purposes of litigation. And Jazz's argument is impossible to reconcile with the statutory criteria that have always governed Orange Book listing.

III. AS A MATTER OF BASIC CLAIM CONSTRUCTION, THE '963 PATENT DOES NOT RECITE METHOD CLAIMS

Only in the last few pages of its brief does Jazz address the key question underlying the proper resolution of this case: whether the district court correctly determined that the '963 patent must be delisted because, as a matter of basic claim construction, it claims "systems" rather than "methods."

The district court correctly held that the '963 patent recites system claims, not method claims. Appx5725. The claim language compelled that conclusion. Every claim recites a "computer-implemented system" with computer components: "computer memories" and a "data processor." Appx98-100. This Court routinely construes "system" claims as systems and distinguishes "systems" from "methods." *See, e.g.*, *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1204 (Fed. Cir. 2010) (noting that "system" claims "do not require the performance of any method steps"); *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005) (a claim that "recites both a system and the method for using that system" is "invalid"). There is no reason to break new ground here. Jazz itself describes the '963 patent's independent claims as "recit[ing] a 'computer implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for

misuse, abuse or diversion.'" OB55.[5] The district court's determination that the '963 patent claims a system was unassailable, and Jazz's arguments to the contrary lack merit.

First, Jazz trumpets that it "submitted unrebutted evidence that the plain and ordinary meaning of 'system' is a 'formulated, regular, or special method or plan of procedure.'" OB56. Not so. Jazz's citations to dictionary definitions of "system," Appx2884, were merely submitted in rebuttal to Avadel's citations of dictionary definitions of "system." As Avadel stated in its answering claim construction brief, "the 'ordinary definition' of the commonly understood word 'system' is 'an integrated assemblage of hardware and/or software elements operating together to accomplish a prescribed end purpose.'" Appx2876 (quoting *ABB Automation Inc. v. Schlumberger Res. Mgmt. Servs., Inc.*, No. 01-cv-077, 2003 WL 1700013, at *4 (D. Del., Mar. 27, 2003), and citing Appx3278-3281 at Appx3281 (*Wiley Electrical and Electronics Dictionary*) (system: "A set of interrelated and/or interdependent components which form a complex whole serving for one or more purposes or functions.")).

[5] Jazz made similar representations elsewhere, characterizing the '963 claims as "computer-implemented systems," Appx3346 (IPR Patent Owner's Response), and stating that "the '963 patent claims recite various hardware implementations of the central computer database," Opp. to Mot. to Dismiss 14, *Jazz Pharm., Inc. v. Watson Laboratories Inc.*, No. 2:14-cv-7757 (D.N.J. Apr. 20, 2015), Dkt. No. 20.

Second, Jazz argues that the patent's use of the word "system" reflects the meaning that Jazz would like to ascribe to it: a "special method or plan of procedure." OB57. But the '963 patent claims do not include any method steps or plans of procedure; instead, they recite different computer *components* of the claimed system—"one or more computer memories" and a "data processor"—that must be capable of various functions. Appx98-100.

Jazz tries to sow confusion, suggesting that "system" has a different meaning depending on whether it refers to the "computer system" described in the specification and claims, "as opposed to the drug distribution system and method of the invention." OB57. But the '963 patent uses "system" and "computer system" interchangeably, including by referring to "Figure 1" using both terms. *Compare* Appx98 (7:40-44) ("The central database … is a relational database on the system of FIG. 1., or a server based system having a similar architecture … ."), *with* Appx95 (2:29-31) (Figure 1 "is a block diagram of a computer system for use in implementing the system and method of the present invention"). Even under Jazz's interpretation of "system," the claims of the '963 patent are directed to a system because they claim a system akin to Figure 1 including the recited hardware. *See*, *e.g.*, Appx79 (Fig. 1); Appx98-99 (cl. 1); Appx5460-5461; *supra* at 53 n.5.

Further, as the district court noted (Appx5724), the existence of method claims in other Jazz patents related to the '963 show that, when Jazz wanted to claim

methods, it knew how to do so—by expressly reciting "methods" and the method steps to be performed. Appx3304 (U.S. Pat. No. 7,765,106 at cl. 1 ("A therapeutic method for treating a patient with a prescription drug ….")); Appx3337 (U.S. Pat. No. 8,457,988 at cl. 1 ("A method of treatment of a narcoleptic patient ….")). In contrast, Jazz chose to recite the '963 patent claims as systems, as Jazz has represented in other proceedings. *See supra* at 53 n.5.

Third, Jazz argues that the district court "never addressed the evidence that articulated the plain meaning of 'system,' versus 'computer system,' or made the requisite finding based on the intrinsic record." OB57. This argument fails. The district court cited Avadel's evidence of the plain and ordinary meaning of the word "system" and found that the term meant "an assemblage of components that together operate to accomplish the prescribed purpose." Appx5723. The district court also rejected Jazz's "strained" arguments that a "system" and a "method" mean the same thing. Appx5724-5725 (citing Appx5463 (93:21) (Jazz's *Markman* arguments)); Appx3423-3446 at Appx3444). Accordingly, the district court properly found that "the claims of the '963 patent are directed to systems, not methods"—much less methods of using a drug. Appx5725.[6]

[6] Even under Jazz's wayward construction, the claims would be "methods of using a *computer-implemented system*," Appx5722 (emphasis added), not "method[s] of using [a] *drug*," 21 U.S.C. § 355(c)(3)(D)(ii)(I) (emphasis added).

* * * * *

Jazz's tenuous appeal falters at every turn. Its '963 patent clearly claims a computer system for managing the distribution of Xyrem, not a method of using that drug. As a matter of patent law, plain statutory language, and common sense, the '963 patent should be delisted. For over a year now, Jazz has managed keep Avadel's superior, one-dose regimen off the market, to the great detriment of narcolepsy patients (who are left with only Jazz's two-dose sleep-disrupting option)—based on a patent that is not remotely a drug or a "method of using" a drug. Congress provided a delisting mechanism for precisely such situations. The district court got it right.

CONCLUSION

The district court's injunction order should be affirmed, and this Court should lift its stay of that injunction as soon as possible.

Dated: January 13, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1) and Federal Circuit Rule 32(b)(3), I hereby certify that the foregoing response complies with the type-volume limitations in Federal Circuit Rule 32(b)(1) because it contains 13,992 words, excluding the exempted parts under Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

I further certify that this response complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because this response was prepared using Microsoft Word 365 in 14-point Times New Roman font.

/s/ Kenneth G. Schuler
Kenneth G. Schuler

Counsel for Appellee
Avadel CNS Pharmaceuticals, LLC

ADDENDUM

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21 U.S.C. § 355(c)(3)(D)(ii)(I)

§ 355. New drugs

* * *

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

* * *

(3) …

* * *

(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY

* * *

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL. —If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.