In the
United States Court of Appeals
For the Seventh Circuit

No. 05-4608

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

GENENDO PHARMACEUTICAL, N.V.,

Defendant-Appellant.

Appeal from the United States District Court for the
Northern District of Illinois, Eastern Division.
No. 03 C 6495—**James F. Holderman**, *Chief Judge.*

ARGUED SEPTEMBER 6, 2006—DECIDED MAY 10, 2007

Before ROVNER, EVANS, and SYKES, *Circuit Judges.*

ROVNER, *Circuit Judge.* This case involves Genendo Pharmaceutical's attempt to import prescription drugs intended for sale in other countries into the United States for repackaging and distribution. Genendo maintains that the importation is authorized pursuant to certain statutory exemptions for drugs being repackaged within the United States. The district court disagreed, and granted the United States' motion for seizure and condemnation of the drugs, as well as a permanent injunction barring further importation.

I.

Genendo, located in Curaçao, Netherlands Antilles, purchases, trades, and sells pharmaceuticals. One portion of its business includes obtaining prescription drugs overseas and importing them into the United States for resale. Some of the drugs it imports were originally intended for sale outside of the United States. As relevant here, in September 2003, Genendo imported 60 boxes of prescription Lipitor containing 10 milligram tablets of Lipitor, and 48 boxes containing 20 milligram tablets of Lipitor.[1] Lipitor is manufactured by Pfizer, Incorporated and is used to treat high cholesterol. Genendo purchased the Lipitor in Brazil in order to import it into the United States.

Before importing the Lipitor, Genendo filed an action for a declaratory judgment that its importation of Lipitor was permissible under the Federal Food, Drug, and Cosmetic Act ("the FDCA"). 21 U.S.C. §§ 301-399. The United States successfully moved to dismiss the action on the grounds that there was not yet an agency action ripe for review. Several months later, Genendo imported, and the government seized, the Lipitor.

At issue is whether the seized Lipitor is an "unapproved new drug," *see* 21 U.S.C. § 355(a), because it does not comply in certain respects with the existing FDA-approved New Drug Application for Lipitor. The new drug approval process is one piece of the FDCA's comprehensive scheme regulating the manufacture, sale, and importation of prescription drugs. Before a drug is introduced into interstate commerce, a drug manufacturer must obtain FDA approval (specific to each drug and each manufac-

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[1] The action initially also involved 24,990 tablets of 40 milligram Zocor (another cholesterol-lowering drug).

turer) of the manufacturing process, labeling, and packaging of the drug. 21 U.S.C. § 355(b)(1). The approval process addresses the drug's safety and effectiveness, *id.* § 355(b)(1)(A), its chemical composition, *id.* § 355(b)(1)(B), and how it is distributed—i.e., "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing" and the proposed labeling for the drug, *id.* §§ 355(b)(1)(D) & (F). Thus, before gaining FDA approval for Lipitor as a "new drug" under the FDCA, *see* 21 U.S.C. § 321(p), Pfizer submitted a New Drug Application ("NDA") which contains, among other things, detailed specifications regarding the drug's manufacture and packaging. *See* 21 U.S.C. § 355(a) (stating necessity of an approved new drug application).

As relevant here, the NDA for Lipitor specifies the following relating to its manufacture and packaging for sale in the United States: (1) the Lipitor must be manufactured at a Pfizer facility in Loughbeg, Ireland; (2) it must be packaged in either Frieburg, Germany or Vega Baja, Puerto Rico; (3) it must be packed in 100-tablet boxes containing ten blister cards of ten tablets each; and (4) it must be labeled in English. Additionally, the NDA provides for a two-year expiration period for Lipitor distributed in the United States.

At the time the United States seized the Lipitor imported by Genendo, it deviated from the FDA-approved NDA in several important respects. First, although it was manufactured in the listed Pfizer facility in Ireland, it was packaged at a facility in São Paulo, Brazil, instead of one of the NDA-approved facilities in Frieburg, Germany or Vega Baja, Puerto Rico. Secondly, it was packaged in boxes containing thirty tablets, housed on three blister sheets of ten tablets each, and labeled, not in English, but in Portuguese. Lastly, the seized lots of Lipitor were manufactured in January 2003 and February 2003, and bore expiration dates of January 2006 and February 2006, respectively—three years after the manu-

facture date, as opposed to the two-year period required by the NDA.

Genendo believes these deviations from the requirements in the FDA-approved NDA are excused by 21 U.S.C. § 353(a) and its implementing regulation, 21 C.F.R. § 201.150. Genendo claims § 353(a) establishes an exemption from all labeling and packaging requirements in the FDCA, including the NDA requirements, so long as a drug is en route to or being held at an authorized drug repackager. Section 353(a), titled in part "Exemptions and consideration for certain drugs," provides as follows:

> (a) Regulations for goods to be processed, labeled, or repacked elsewhere
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> The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

21 U.S.C. § 353(a).

The regulation promulgated is 21 C.F.R. § 201.150, which provides in pertinent part that a drug that will be repackaged "shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501(b) and 502(b), (d), (e), (f), and (g) of the act" if, among other things, there exists a written agreement—known as a § 201.150 agreement—that ensures the ultimate drugs will not be adulterated or misbranded. *See* 21 C.F.R. § 201.150(a)(2).

At the time it was seized, the imported Lipitor was destined for the Illinois corporation Phil & Kathy's, an FDA-registered repacker and labeler. Genendo had a written § 201.150 agreement with Phil & Kathy's for the repacking and labeling of drugs for sale in the United States. Before trial, the government filed a seizure action for certain drugs held at Phil & Kathy's, and Phil & Kathy's entered into a consent decree resolving the government's claims against it. Although the government also contended in the district court that Genendo's § 201.150 agreement with Phil and Kathy's was inadequate, the court did not reach that issue.

Instead, the district court held a one-day trial, and ultimately ruled on the basis of the uncontested facts that by importing the Lipitor,[2] Genendo had introduced unapproved new drugs into interstate commerce in violation of 21 U.S.C. § 355(a). The court concluded that reading the exemption in § 353(a) as Genendo proposed would eviscerate the protections afforded by the new drug approval process. It thus attempted to harmonize the requirements of the new drug approval process and the § 353(a) exemption by reading the "labeling and packaging requirements" referred to in § 353(a) to apply to general "labeling and packaging," but not the detailed requirements for packaging set forth in the NDA, which the court concluded were not affected by the exemption in § 353(a). The court also granted the government's request for condemnation of the drugs and injunctive relief.

[2] The district court also concluded that the seized Zocor was an unauthorized new drug, but Genendo does not appeal that conclusion.

II.

The sole issue on appeal is whether the seized Lipitor is an unapproved "new drug." *See* 21 U.S.C. § 355(a). Since Genendo admits that the seized Lipitor was not completely compliant with the NDA at the time it was seized, the only relevant question is whether, as Genendo maintains, § 353(a) exempts it from compliance with the NDA. This is a question of statutory interpretation subject to de novo review. *See Disability Rights Wis., Inc. v. Wis. Dep't of Pub. Instruction*, 463 F.3d 719, 724 (7th Cir. 2006). The FDA argues that the labeling and packaging requirements contained in the NDA are a critical piece of the new drug approval process and must be adhered to at all stages of the drug's production and distribution, and that § 353(a) does not change that. Genendo, however, contends that because the Lipitor was en route to an authorized repackager at the time it was seized, it is exempt from all labeling and packaging requirements, including all of those contained in the NDA.

As a threshold matter, we must determine the level of deference to be accorded the FDA's interpretation of § 353(a). As the agency that administers the statute, the FDA claims that its interpretation is entitled to *Chevron* deference. *See Chevron U.S.A., Inc. v. Natural Res. Def. Counsel, Inc.*, 467 U.S. 837 (1984) (explaining deference due agency's interpretation of statute it administers). Genendo, however, claims that the unambiguous language of § 353(a)—directing the Secretary to promulgate regulations exempting certain drugs from "any labeling or packaging requirement of this chapter"—compels the conclusion that the Lipitor is exempt from all labeling and packaging requirements—including those contained in the NDA. According to Genendo, any other interpretation flies in the face of the plain statutory language and is thus undeserving of our deference. In determining

what level of deference to afford the FDA's interpretation, we ask first whether Congress has spoken to the precise question at issue. *Chevron*, 467 U.S. at 842-43. Genendo claims that it has done so in the form of § 353(a), and that the phrase "any labeling and packaging requirement" necessarily ends the matter.

But § 353(a) simply directs "the Secretary" to promulgate regulations exempting drugs en route to a repackager from labeling and packaging requirements; it does not itself provide for a complete exemption. *See Arner Co. v. United States*, 142 F.2d 730, 736 (1st Cir. 1944) ("Had Congress intended an outright exemption of bulk shipments from the labeling requirement without restrictive terms of any sort, there would have been no need for it to provide for regulations formulating the exemption; the law would have simply stated the exemption."). The problem with Genendo's argument is that it largely ignores the fact that the promulgated regulation, § 201.150, sets forth specific labeling and packaging requirements from which drugs being repackaged are exempt. The particular sections of the FDCA referenced in § 201.150 relate to the requirement that the package contain the name and address of the manufacturer or distributor, a statement of the quantity of the contents, the established name of the drug, active and inactive ingredients, and adequate warnings and directions for use. *See* 21 U.S.C. §§ 351(b), 352(b), (d), (e), (f), and (g). Section 201.150 thus does *not* exempt drugs in transit to or at a repackager from *all* labeling and packaging requirements in the Act, as Genendo suggests—simply those listed.

Thus the statute is not so crystal clear as Genendo insists. Genendo's argument flows from an unstated belief that the word "any" in § 353(a) necessarily means "all." But that is not so. On the contrary, the first definition given for the word any is "one, a, an, or some." *Webster's*

Unabridged Dictionary of the English Language 96 (2d ed. 2001). Although the statute could be read as if any meant all (the fourth possible definition given for the word "any"), it could also be read to give effect to the aforementioned definition of "any"—as directing the Secretary to promulgate regulations exempting drugs in transit to a repackager from *some* labeling and packaging requirements contained in the FDCA. *See First Bank & Trust v. Firstar Info. Servs., Corp.*, 276 F.3d 317, 325-26 (7th Cir. 2001) (rejecting argument that phrase "any services" in contract necessarily meant "all services" and concluding that phrase was ambiguous). Given that § 201.150 exempts drugs in transit only from specified labeling and packaging requirements, the Secretary apparently understood it to mean the latter.[3]

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[3] After argument, Genendo filed a letter of supplemental authority pursuant to Federal Rule of Appellate Procedure 28(j), calling the panel's attention to the recently decided Supreme Court case *Massachusetts v. E.P.A.*, 127 S. Ct. 1438 (2007). In *Massachusetts*, the Court interpreted the phrase "any air pollutant" in the Clean Air Act to include carbon dioxide, reasoning in part that the use of the word "any" suggested that the statute was intended to require regulation of *all* air pollutants. Genendo argues that *Massachusetts* stands for the proposition generally that the use of the word "any" in a statute necessarily means "all." *Massachusetts*, however, is not so broad. First, the Court's interpretation of the phrase "any air pollutant" was guided by the Clean Air Act's "sweeping definition of 'air pollutant,'" a definition that embraced "all airborne compounds of whatever stripe . . . through the *repeated* use of the word 'any.'" *Id.* at 1460 (emphasis added). The exemption in § 353(a) has no such "sweeping" language, nor does it contain anything else to convince us that the word "any" necessarily means "all." Nor does *Massachusetts* itself stand for such a proposition. Indeed, the Court cited with approval *Dep't of Hous. & Urban Dev. v. Rucker*, 535 U.S. 125 (2002), where it observed that the word "any" "has

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Reading the statute in isolation, Genendo's interpretation may be a plausible one, but so too is the FDA's, particularly in light of the "'well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health.'" *United States v. Baxter Healthcare Corp.,* 901 F.2d 1401, 1408 (1990) (quoting *United States v. Article of Drug . . . Bacto-Unidisk* . . ., 394 U.S. 784, 798 (1969)). In short, there is enough ambiguity in the statute that we ask only whether the FDA's interpretation is based on a permissible construction of the statute. *Chevron*, 467 U.S. at 843. Section 201.150's provision exempting drugs in transit from only certain labeling and packaging requirements is a permissible exercise of the authority delegated by the statute, and is consistent with the public health concerns animating the new drug approval process and the FDCA as a whole. *See id.* at 843, 866 (agency's interpretation comporting with purposes of underlying Clean Air Act Amendments is permissible given ambiguity in statute). Thus, unless the regulation (and the FDA's interpretation of it) is "arbitrary, capricious, or manifestly contrary to the statute," we will defer to it. *Id.* at 843-44.

We cannot say that the FDA's interpretation of the regulation and statute is "arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 843. Indeed, the FDA's interpretation makes good sense given that § 201.150 enumerates particular labeling and packaging

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[3] (...continued)
an expansive meaning, that is, *one or some*, indiscriminately of whatever kind." (emphasis added). *Massachusetts* interpreted a particular statute in an entirely different context, and concluded that in that case, "any" meant "all." The Court's holding does not in any way imply that in every case "any" means "all."

requirements from which drugs in transit are exempt, and the NDA requirements are not among those enumerated. This understanding of the statute and regulation together is in keeping with our observation in *Baxter* that the new drug approval process "illustrates a congressional view that the way in which drugs are mixed and packaged is no less important than the chemical makeup of the drugs at issue," 901 F.2d at 1411. As the FDA points out, this precise packaging operation is subject to compromise if Genendo is given carte blanche to disregard the specifications in the NDA. Genendo maintains that the requirement in both § 353(a) and § 201.150 that the ultimate repackaged drugs cannot be adulterated or misbranded protects the consumer from any deviations from the NDA that occur before the drugs are repackaged. But even assuming a flawless repackaging process at Phil & Kathy's pursuant to a satisfactory § 201.150 agreement (an assumption the government contests), certain deviations from the NDA's requirements are never rectified despite the repackaging. Notably, the fact that the Lipitor was packaged at an unapproved facility in Brazil can never be brought into compliance with the NDA (unlike the other deviations from the NDA such as the Portuguese labeling, improper expiration dates, and numbers of tablets in blister packs, which could theoretically be later rectified). It would be odd indeed for the FDA to go to such lengths to set up the process whereby facilities are approved for packaging new drugs, and yet allow drugs that will be repackaged to be packaged in an unapproved facility. If such a result were intended, we believe that the statute and accompanying regulation would say so explicitly.

Genendo's reliance on a Third Circuit case, *United States v. Kaybel*, 430 F.2d 1346 (3d Cir. 1970), does not convince us otherwise. In *Kaybel* the court overturned a wholesale drug distributor's conviction for introducing an unap-

proved new drug into interstate commerce. The court in *Kaybel* rejected the government's claim that the distributor needed to obtain approval of an additional new drug application before repacking a drug that complied in all respects with an already approved NDA from 500-unit bottles into 100-unit bottles. *Id.* at 1347. Not only does *Kaybel* not deal with the exemption provision in § 353(a), its application to Genendo's situation is further limited by the fact that the distributor in *Kaybel* was repackaging a drug that was *compliant in all respects* with the NDA, not attempting to remedy noncompliance through repackaging. In short, we think *Kaybel* is far less applicable than Genendo believes. Moreover, the primary rationale in *Kaybel*—that other mechanisms exist to prevent contamination of drugs by repackagers—does not extend to the situation where drugs are first packaged at an unapproved facility that lacks the FDA oversight of the packaging facilities listed in the NDA. *See In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 789-90 (8th Cir. 2006) (explaining importance of FDA oversight and FDCA labeling requirements in excluding "noncompliant and potentially unsafe pharmaceuticals").

The FDA's interpretation of § 353(a) and § 201.150 is entitled to deference, and it is neither arbitrary nor capricious. Although § 353(a) may have been interpreted as Genendo suggests, it is also open to the construction provided by the FDA, and that construction is entitled to deference under *Chevron* and is consistent with the language of § 201.150. It also comports with the underlying purposes of the FDCA, which exists to protect aspects of "the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection." *Arner*, 142 F.2d at 736; *see also Canadian Import*, 470 F.3d at 790 (labeling requirements are "manifestation of a congressional plan to create a 'closed system' designed to guarantee safe and effective drugs

for consumers in the United States"). In sum, the exemption in § 353(a), as implemented by § 201.150, does not excuse compliance with an FDA-approved NDA, and thus the seized Lipitor, which Genendo concedes is noncompliant, is an unapproved new drug. *See* 21 U.S.C. § 355(a).

III.

For the foregoing reasons, we affirm the judgment of the district court.

A true Copy:

Teste:

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Clerk of the United States Court of Appeals for the Seventh Circuit