IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
February 25, 2011

Lyle W. Cayce
Clerk

No. 10-50031

MEDICAL CENTER PHARMACY; APPLIED PHARMACY;
COLLEGE PHARMACY; MED SHOP TOTAL CARE PHARMACY;
PET HEALTH PHARMACY INCORPORATED;
PLUM CREEK PHARMACEUTICALS INCORPORATED;
PREMIER PHARMACY; UNIVERSITY COMPOUNDING PHARMACY;
VETERINARY PHARMACIES OF AMERICA;
WOMEN'S INTERNATIONAL PHARMACY INCORPORATED,

Plaintiffs–Appellants

v.

ERIC H. HOLDER, JR., U.S. ATTORNEY GENERAL, In his official capacity as Attorney General, United States Department of Justice;
KATHLEEN SEBELIUS, In her official capacity as Secretary of the Department of Health and Human Services;
MARGARET A. HAMBURG, In her official capacity as Commissioner of the United States Food and Drug Administration,

Defendants–Appellees

Appeal from the United States District Court
for the Western District of Texas

Before WIENER, GARZA, and PRADO, Circuit Judges.

EDWARD C. PRADO, Circuit Judge:

This case is before us for the second time. In our first opinion,[1] we held that "compounded" drugs are "new" drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 300–399a, but that they are exempt from the FDCA's adulteration, misbranding, and new-drug-approval provisions if they comply with the conditions set forth in 21 U.S.C. §§ 353a and 360b(a).

On remand, the defendant, the Food and Drug Administration ("FDA"), argued that our first opinion enlarged its authority to inspect the records of pharmacies that compound drugs. Before the first appeal, the district court had ruled that state-law-compliant pharmacies are exempt from FDA records inspections under 21 U.S.C. § 374(a)(2)(A). The district court agreed with the FDA's argument on remand, however, and entered a new judgment declaring that, notwithstanding § 374(a)(2)(A), the FDA may conduct limited inspections of pharmacy records to determine if pharmacy-compounded drugs comply with the conditions set forth in §§ 353a and 360b(a).

The plaintiffs, which are ten pharmacies that compound prescription drugs ("the Pharmacies"), appeal the district court's second inspection ruling. They contend, among other things, that because the FDA did not appeal the original inspection ruling, it forfeited the inspection issue, and therefore the district court erred by reopening the issue on remand. We agree that the FDA forfeited the inspection issue, and thus we vacate and remand.

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[1] *See Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008).

I. FACTUAL AND PROCEDURAL HISTORY

In 2005, the Pharmacies filed this lawsuit for declaratory and injunctive relief, challenging the authority of the FDA to regulate compounded drugs under the FDCA. They sought four declaratory judgments, two of which are relevant to this appeal: (1) "that compounded drugs are not 'new drugs' or 'new animal drugs' under [the FDCA], and on this basis, that they are not subject to the requirements and prohibitions imposed by the FDCA on such drugs," and (2) "that the Pharmacies' compliance with 21 U.S.C. § 374(a)(2)(A) makes them exempt from the heightened 'records inspection' authorized by § 374(a)(1)." *Med. Ctr. Pharmacy*, 536 F.3d at 392.

The district court granted summary judgment to the Pharmacies on both declarations. *See Med. Ctr. Pharmacy v. Gonzales*, 451 F. Supp. 2d 854 (W.D. Tex. 2006). Regarding the first declaration, the court ruled that compounded drugs are "implicitly exempt from the new drug definitions," *id.* at 858, and are "implicitly exempt from the new drug approval process." *Id.* at 863. Regarding the other declaration, the court held that under § 374(a)(2)(A), "if a pharmacy is compliant with local laws, and dispenses drugs pursuant to the receipt of a prescription from a licensed practitioner, and compounds in the regular course of its own individualized business, the pharmacy is exempt from [FDA records inspections]." *Id.* at 866. Further, the court ruled that "[i]n order to conduct a [records] inspection of a pharmacy [that] meets the requirements found in the exemption, the FDA must demonstrate why the pharmacy does not qualify for the exemption." *Id.* The court found that because the FDA had failed to show that the Pharmacies did not qualify for the exemption, the Pharmacies were entitled to protection from future records inspections. *Id.*

The FDA then filed a motion to alter or amend the judgment, challenging the district court's rulings on summary judgment. On the inspection issue, the FDA argued that because of the conditions in § 353a, the Pharmacies

> may not compound drugs free from FDA inspection of their records simply by meeting the criteria of section 374(a)(2)(A).
>
> . . . Whatever may have been drawn from section 374(a)(2)(A) with regard to inspection of compounding pharmacies prior to the enactment of section 353a, the construction of the inspection exception must now be informed by the specific, later enacted, requirements of section 353a applicable as a result of this court's holding.

The Pharmacies contested this point in their response. In its reply, the FDA reiterated its position that "the [FDCA]'s inspection provisions must be read to allow full inspections to determine compliance, or lack thereof, with section 353a." The district court denied the post-judgment motion.

The FDA appealed. Despite raising the inspection issue in its motion to alter or amend, the FDA appealed only the district court's ruling on the new-drug issue. It did not challenge the inspection declaration, and, in its brief, it specifically disavowed any intent to raise the inspection issue:

> The district court also ruled that, on the basis of the evidence before it, FDA could not inspect the records of the ten plaintiff pharmacies "unless it demonstrates that they are no longer meeting the requirements set forth in [§ 374(a)(2)(A)]." That ruling is not here at issue.

On appeal, we reversed the district court's ruling on the new-drug issue, holding instead that compounded drugs are "new" drugs under the FDCA, but that they are exempt from the FDCA's substantive provisions if they comply with the conditions in §§ 353a and 360b(a). *Med. Ctr. Pharmacy*, 536 F.3d at 394. Therefore, we "VACATED and REMANDED for further proceedings as

appropriate in accordance with this opinion." *Id.* at 409. Our opinion did not address the inspection issue, except to note that "[n]either party appeals the holding[] regarding 'records inspection.'" *Id.* at 393.

But, on remand, the FDA argued that our clarification of the statutory scheme for compounded drugs necessitated a reevaluation of the district court's original inspection declaration. The district court agreed, and it entered a new judgment that declared that the FDA has the statutory authority to conduct limited inspections of the records of pharmacies "to determine whether drugs compounded [in those pharmacies] are eligible for the exemption provided by §[§] 353a [and] 360b(a)."

The Pharmacies appeal from this judgment, arguing that the FDA, by failing to appeal the original inspection declaration, forfeited the inspection issue, and therefore the district court violated the law-of-the-case doctrine or, alternatively, the waiver doctrine when it reversed itself on remand.

II. STANDARD OF REVIEW

Whether the law-of-the-case doctrine or its related doctrines, including the waiver doctrine, forecloses any of the district court's actions on remand is a question of law that we review de novo. *See Gen. Universal Sys., Inc. v. HAL, Inc.*, 500 F.3d 444, 453 (5th Cir. 2007) (citation omitted).

III. ANALYSIS

"The law-of-the-case doctrine 'posits that when a court decides upon a rule of law, that decision should continue to govern the same issue in subsequent stages in the same case.'" *United States v. Castillo*, 179 F.3d 321, 326 (5th Cir. 1999) (quoting *Arizona v. California*, 460 U.S. 605, 618 (1983)). Therefore, "an issue of . . . law decided on appeal may not be reexamined by the district court

on remand or by the appellate court on a subsequent appeal."[2] *United States v. Lee*, 358 F.3d 315, 320 (5th Cir. 2004) (citation and internal quotation marks omitted). Conversely, an issue that is not expressly or implicitly decided on appeal does not become part of the law of the case. *Alpha/Omega Ins. Servs., Inc. v. Prudential Ins. Co. of Am.*, 272 F.3d 276, 279 (5th Cir. 2001) ("[U]nlike res judicata, the law of the case doctrine applies only to issues that were actually decided, rather than all questions in the case that might have been decided, but were not.") (citation omitted).

This rule, however, is qualified by the waiver doctrine, which holds that an issue that could have been but was *not* raised on appeal is forfeited and may not be revisited by the district court on remand. *See Castillo*, 179 F.3d at 326 ("The waiver doctrine bars consideration of an issue that a party could have raised in an earlier appeal in the case.") (citing *Brooks v. United States*, 757 F.2d 734, 739 (5th Cir. 1985)); *see also Lee*, 358 F.3d at 321 ("[T]he rule bars litigation of issues decided by the district court but foregone on appeal or otherwise waived . . . .") (citation omitted); *id.* at 323 ("[I]ssues not arising out of this court's ruling [on appeal] and not raised in the appeals court, which could have been brought in the original appeal, are not proper for reconsideration by the district court below." (emphasis omitted)) (citation omitted). The waiver doctrine, like the law-of-the-case doctrine, "serves judicial economy by forcing parties to raise issues whose resolution might spare the court and parties later rounds of remands and appeals." *Castillo*, 179 F.3d at 326 (citation and internal quotation

[2] The law-of-the-case doctrine is called the "mandate rule" when it embodies the policy that a district court on remand must obey the letter and the spirit of the earlier decision of an appeals court. *See United States v. Becerra*, 115 F.3d 740, 753 (5th Cir. 1998), *abrogated on other grounds as stated in United States v. Farias*, 481 F.3d 289, 297 (5th Cir. 2007).

marks omitted). But it "differs from the law-of-the-case doctrine in that it arises as a consequence of a party's inaction, not as a consequence of a decision on our part."[3] *Id.* (citation omitted).

For example, in *General Universal Systems*, the plaintiff, GUS, brought several claims, including claims for the misappropriation of trade secrets, against two sets of defendants (the "Hal Defendants" and the "Customer Defendants"). 500 F.3d at 448. The magistrate judge entered summary judgment on most of the claims, including the misappropriation claims, in favor of the defendants. *Id.* GUS appealed, but failed to brief any arguments on its claims against the Customer Defendants. *Id.* at 453. We reversed and remanded with respect to the misappropriation claim against the HAL defendants. *Id.* at 448. On remand, the district court concluded that the misappropriation claim against the Customer Defendants had been forfeited and granted summary judgment to the Customer Defendants. *Id.* GUS appealed for a second time, but we upheld the district court's decision, stating:

> Our prior opinion and the circumstances it embraces disposed of any issues related to the Customer Defendants through waiver. By failing to brief any arguments against the Customer Defendants, GUS waived any claims against the Customer Defendants. While our prior opinion did not explicitly address the Customer Defendants nor any claim by GUS brought against them, this is not surprising based on the absence of any arguments against the Customer

[3] Unfortunately, since *Castillo*, we have often failed to distinguish the waiver doctrine from the law-of-the-case doctrine. *E.g.*, *Lee*, 358 F.3d at 321 (referring to the waiver doctrine as the mandate rule); *Gen. Universal Sys.*, 500 F.3d at 453–54 (same); *see also* 18B CHARLES ALAN WRIGHT, ARTHUR R. MILLER & EDWARD H. COOPER, FEDERAL PRACTICE AND PROCEDURE § 4478.6 (2d ed. 2002 & Supp. 2010) (explaining that the waiver doctrine is often confused with the law-of-the-case doctrine). Regardless of nomenclature, our cases are consistent; they all hold that if an issue was decided by the district court but was not appealed, the issue is forfeited, and the district court may not reconsider the issue on remand.

> Defendants in GUS's brief in the original appeal. GUS's brief dealt only with arguments against the summary judgment granted to the HAL Defendants.

Id. at 453.

Likewise, in *United States v. Griffith*, 522 F.3d 607 (5th Cir. 2008), two criminal defendants objected at sentencing to their presentence investigation reports; one defendant requested a "mitigating role" reduction in his sentence, while the other challenged an "obstruction of justice" enhancement. *Id.* at 609. The district court overruled both objections and imposed an "aggravating role" enhancement for each defendant. *Id.* The defendants appealed the new role enhancements, but they did not raise their mitigating-role and obstruction-of-justice objections. *Id.* We reversed the aggravating-role enhancements and remanded for resentencing. *Id.* At resentencing, the defendants raised their original objections, but the district court refused to reopen those objections. *Id.* at 609–10. The defendants again appealed, but we upheld the district court's decision, holding that the defendants' original objections

> fit squarely within the waiver doctrine . . . . Neither defendant has demonstrated why he was unable to appeal his issue in the initial appeal. Each did appeal the leadership enhancements, which we reversed. It does not follow that because they appealed one aspect of the sentence, they preserved every other objection for review on remand. In fact, because they had already objected in the district court on those very grounds, they had every incentive and opportunity to appeal the sentence on those grounds as well. Because they did not, the arguments are waived.

Id. at 610. (citations omitted).

The instant case is no different; it, too, fits squarely within the waiver doctrine. The FDA failed to raise its objection to the district court's original inspection declaration in the first appeal. Indeed, the FDA expressly disavowed

any intent to raise the inspection issue, and, in our first opinion, we recognized the FDA's waiver by noting that "[n]either party appeals the holding[] regarding 'records inspection.'" Therefore, the FDA forfeited the inspection issue, and the district court erred by reversing its prior inspection ruling on remand.[4]

The FDA argues that it "presented its new interpretation of its inspection authority in a timely manner" because its "earlier position," which caused it to forgo appeal, was "based on its assumption—shared by the Pharmacies—that section 353a was invalid in its entirety." Our first opinion, the FDA contends, "changed the controlling law" by resurrecting § 353a, thereby "necessitat[ing] [the] FDA's reinterpretation" of its inspection authority.

This counter-argument is not supported by the record, which shows that prior to the first appeal, the FDA believed that § 353a was valid. In its post-judgment motion, the FDA argued that because of the conditions set forth in § 353a, the Pharmacies "may not compound drugs free from FDA inspection of their records simply by meeting the criteria of section 374(a)(2)(A)." After the Pharmacies opposed this argument in their response, the FDA argued in its reply brief that "the [FDCA]'s inspection provision must be read to allow full inspections to determine compliance, or lack thereof, with section 353a." The fact that the FDA raised these arguments prior to the first appeal directly contradicts its present assertion—that it had assumed that § 353a was invalid, thereby causing it to forgo appeal of the inspection issue. Moreover, it proves

[4] Given our occasional failure to treat the waiver doctrine as a separate rule of law, it is not clear whether an appeals court may override the waiver doctrine by expressly leaving an issue open. We note only that in this case, we did not expressly leave the inspection issue open in our first opinion. *See* 18B WRIGHT, MILLER & COOPER, *supra* note 3, § 4478.3 ("A remand made without deciding anything, apart from directing further proceedings, determines only that the further proceedings must be had . . . .").

that the FDA foresaw that its argument regarding the statutory scheme for compounded drugs could necessitate a reevaluation of the inspection issue. Therefore, the FDA "had every incentive and opportunity to appeal . . . on those grounds as well," *Griffin*, 522 F.3d at 610, and the inspection issue "could have been brought in the original appeal." *Lee*, 358 F.3d at 323 (emphasis omitted). Because the FDA decided not to appeal the issue, the issue was forfeited and was "not proper for reconsideration by the district court below." *Id.*

"Only plain error justifies departure from the waiver doctrine." *Castillo*, 179 F.3d at 326. Section 374(a)(2)(A) is not ambiguous on its face, and §§ 353a and 360b(a) do not expressly contradict, amend, or refer to § 374(a). Thus, we cannot say that the district court's original inspection declaration was plainly erroneous.

IV. CONCLUSION

The FDA forfeited the inspection issue, and the district court violated the waiver doctrine by reopening the issue. Accordingly, we vacate and remand.

VACATED and REMANDED.