United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 11, 2025 Decided June 26, 2026

No. 23-5311

NORWICH PHARMACEUTICALS, INC.,
APPELLANT

v.

ROBERT F. KENNEDY, JR., IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:23-cv-01611)

Andrew D. Prins argued the cause for appellant. With him on the briefs were *Matthew S. Murphy*, *Nicholas L. Schlossman*, *Rachael L. Westmoreland*, and *Lia Rose Barrett*. *Aziz Burgy* and *Chad A. Landmon* entered appearances.

J. Kain Day, Attorney, U.S. Department of Justice, argued the cause for federal appellees. With him on the brief were *Brett A. Shumate*, Assistant Attorney General, and *Daniel Tenny*, Attorney. *Joshua Dos Santos* and *Benjamin C. Wei*, Attorneys, entered appearances.

Bryan Killian argued the cause for appellee Salix Pharmaceuticals, Inc. With him on the brief were *Douglas Hastings* and *Brendan J. Anderson*.

Before: PILLARD, WALKER and GARCIA, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* WALKER.

WALKER, *Circuit Judge:* This case concerns a district court's final judgment. The judgment identified a drug application by its specific number and said that the FDA cannot approve the application until a specific date.

The question is whether that judgment implicitly permits the FDA to approve an amended version of that specific application before that specific date.

Because it doesn't, we affirm.

I. Background

A. Litigation in Delaware

Salix Pharmaceuticals invented a drug called Xifaxan. It helps people suffering from irritable bowel syndrome with diarrhea and from hepatic encephalopathy.[1]

Norwich Pharmaceuticals wants to market a generic competitor to Salix's drug. So Norwich filed an Abbreviated New Drug Application with the Food and Drug Administration. The FDA gave that ANDA the number 214369.

[1] Hepatic encephalopathy is a type of brain dysfunction due to liver disease.

Salix believed that Norwich's '369 ANDA infringed Salix's patents. So Salix sued Norwich in the United States District Court for the District of Delaware. That court held that Norwich's '369 ANDA infringed Salix's patents related to the treatment of hepatic encephalopathy, but that the rest of Salix's patents at issue — including for irritable bowel syndrome with diarrhea — were invalid as obvious.

The Delaware District Court then asked Norwich and Salix to propose language for the court's final judgment. Both parties agreed that the court's findings meant that the FDA could not approve Norwich's original '369 ANDA until Salix's hepatic-encephalopathy patents expire in October 2029. But beyond that the parties presented "starkly conflicting" views. JA 154.

Norwich wanted a final judgment that would allow the FDA to immediately approve Norwich's '369 ANDA if Norwich amended it to remove labeling related to hepatic encephalopathy. Salix disagreed. It wanted a judgment that would "apply to 'Norwich's ANDA,' period." JA 135.

The Delaware District Court rejected Norwich's proposal. The court instead agreed with Salix to bar the FDA from approving Norwich's '369 ANDA until the expiration of Salix's hepatic-encephalopathy patents in October 2029. The court's final judgment said:

> Pursuant to 35 U.S.C. § 271(e)(4)(A), it is hereby ordered that the effective date of **any final approval by the Food and Drug Administration ("FDA") of Norwich's ANDA No. 214369 is to be a date not earlier than** the date of expiration of the last to expire of the [hepatic-encephalopathy] Patents (currently **October 2, 2029**), plus any regulatory exclusivity to which Plaintiffs are or become entitled.

JA 135–36 (quoting Dkt. 4-5 at 3) (emphases added).

Norwich then filed an amended '369 ANDA with the FDA that no longer sought approval of the drug for treatment of hepatic encephalopathy. The next day Norwich filed a Rule 60(b) motion asking the Delaware District Court to change its judgment. Norwich argued that "the predicate for ordering [the] FDA to delay the effective date of the approval of Norwich's ANDA . . . no longer exists" because of Norwich's amendments to its '369 ANDA. JA 78.

The Delaware District Court denied Norwich's motion. It reasoned that Norwich should not be able to "litigate a case through trial and final judgment based on a particular ANDA, and then, after final judgment, change the ANDA to what it wishes it had started with, and win in a summary proceeding." JA 116.

On appeal to the Federal Circuit, Norwich argued that the Delaware District Court should not have ordered the FDA to delay final approval of its amended ANDA until October 2029. The Federal Circuit agreed with Norwich's understanding of the Delaware District Court's final judgment — i.e, that the final judgment "restricted final approval of the entire ANDA, including the non-infringing indication, until 2029." *Salix Pharmaceuticals., Ltd. v. Norwich Pharmaceuticals Inc.*, 98 F.4th 1056, 1068 (Fed. Cir. 2024). But the Federal Circuit affirmed the Delaware District Court, noting that the District Court's final judgment "said nothing that would prevent approval [by the FDA] of a *new* non-infringing ANDA." *Id.* (emphasis added).

B. Litigation in the District of Columbia

The FDA declined to grant final approval of Norwich's amended '369 ANDA. Instead, the FDA granted only

tentative approval. It reasoned that the Delaware District Court's final judgment barred it from granting final approval until October 2029.[2]

Norwich sued the FDA in the United States District Court for the District of Columbia. It claimed that the FDA acted arbitrarily, capriciously, or otherwise contrary to law when it did not grant final approval of Norwich's amended '369 ANDA.

The district court granted summary judgment to the FDA and intervenor Salix.

Norwich appealed.

We affirm.[3]

II. Analysis

In this appeal, Norwich does not challenge the lawfulness of the Delaware District Court's judgment. Nor does Norwich argue that the FDA was free not to follow that judgment. Rather, Norwich says that the FDA misread the judgment to require a delay of Norwich's amended ANDA until October 2029.

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[2] According to the government, the FDA issued a new tentative-approval decision after the Federal Circuit's opinion, relying on the "same reasoning" as the prior decision. Gov't Br. 28 n.6. That new decision therefore repeats the same alleged errors as the prior one, "preserv[ing], rather than moot[ing]" the present controversy. *Union of Concerned Scientists v. Nuclear Regul. Comm'n*, 711 F.2d 370, 379 (D.C. Cir. 1983) (citation omitted).

[3] We also affirm the district court's denial of Norwich's motion for a preliminary injunction.

A. The FDA Applied The Plain Meaning Of The Final Judgment

Norwich's interpretation of the Delaware District Court's final judgment is incorrect. The final judgment listed Norwich's '369 ANDA by number. JA 68. And it ordered a delay of that ANDA's final approval until October 2029. *Id.* ("the effective date of any final approval by the Food and Drug Administration ('FDA') of Norwich's ANDA No. 214369 is to be a date not earlier than the date of expiration of the last to expire of the [hepatic-encephalopathy] Patents (currently October 2, 2029)"). That means Norwich's '369 ANDA cannot be approved until October 2029. And because "Norwich's ANDA, even as amended, is still" the '369 ANDA, "the FDA's determination tracks the most straightforward reading of the final judgment." JA 154.

B. Context Confirms The Final Judgment's Plain Text

"That plain-language reading of the final judgment is reinforced . . . by the extensive briefing and argument that came before and after its entry." *Id.*

Let's start with Norwich's briefing before the Delaware District Court's final judgment. Norwich asked for express language allowing the FDA to immediately approve an amended '369 ANDA. But the Delaware District Court refused, explaining that an amended '369 ANDA "is immaterial to this analysis" because it "is not before me." Dkt. 4-6 at 2. By *refusing* to issue a final judgment saying what Norwich wanted the judgment to say, the court *refused* to issue a judgment saying what Norwich now says the judgment means.

Now consider Norwich's briefing after that final judgment. Norwich repeatedly said in its Rule 60(b) motion

that the Delaware District Court's judgment does *not* mean what Norwich now says it means:

- "Here, the circumstances that led to the entry of **the order blocking FDA approval** – Norwich's proposed ANDA labeling for the HE Indication – no longer exists." JA 90 (emphasis added).

- "[I]t is no longer equitable to prospectively **enjoin the approval of Norwich's Amended ANDA**." JA 90 (emphasis added).

- "Norwich invokes Rule 60(b)(5) to remove **the bottleneck preventing FDA's approval of Norwich's Amended ANDA**." JA 91 (emphasis added).

- "**Foreclosing FDA's approval of Norwich's Amended ANDA for seven years** poses an extreme hardship to Norwich." JA 94 (emphasis added).

- "**The prohibition on FDA's approval of Norwich's ANDA Product** is also detrimental to the public interest . . . ." JA 94 (emphasis added).

- "The Court should modify the relief granted in the Judgment . . . to remove **the absolute prohibition on FDA's approval of Norwich's Amended ANDA before October 2, 2019**." JA 83 (emphasis added).

Finally, recall that the Delaware District Court *denied* Norwich's 60(b) motion to amend its final judgment "[f]oreclosing FDA's approval of Norwich's Amended ANDA for seven years." Norwich's Rule 60(b) Opening Br. at 17 (JA 94). That means Norwich is now arguing "that the final judgment is best read *implicitly* to include the qualifying language that the court *explicitly* declined to include — twice."

JA 156. In addition, it is asking us to read the final judgment contrary to the Federal Circuit's interpretation of it. *See Salix Pharmaceuticals*, 98 F.4th at 1068 ("*[T]he order restricted final approval of the entire ANDA*, including the non-infringing [part], until 2029.") (emphasis added).

We decline to do so. The FDA read the Delaware District Court's final judgment correctly — as did Norwich at the time, as did the Federal Circuit, and as did the District Court for the District of Columbia.

C. *Ferring B.V.* Does Not Help Norwich

Norwich points to a final judgment by the district court in *Ferring B.V. v. Watson Laboratories, Inc.-Florida*, 764 F.3d 1382 (Fed. Cir. 2014). That final judgment distinguished between an original ANDA and an amended ANDA "when deciding the issue of infringement," *id.* at 1390–91, just as Norwich believes the Delaware District Court did here. As the Federal Circuit explained, the *Ferring B.V.* district court held "that [the original ANDA] infringed" certain patents but said the defendant's "[s]tipulat[ion] to amend its ANDA . . . moots Plaintiff's Complaint with regard to [defendant's] proposed ANDA amendment." *Id.* at 1387 (quoting JA 18).

Unlike in *Ferring B.V.*, however, the final judgment by the Delaware District Court here made no mention of an amended ANDA. In addition, the context in *Ferring B.V.* was different because the defendant there had promised *during trial* to amend its ANDA. 764 F.3d at 1386. Here, Norwich "litigate[d] a case through trial and final judgment based on a particular ANDA, and then, after final judgment, [tried to] change the ANDA to what it wishes it had started with" in an attempt to "win in a summary proceeding." JA 116.

Though we cannot know what the district court in *Ferring B.V.* would have done in our case's circumstances, we know what the Delaware District Court did. It *twice* rejected Norwich's proposal to expressly exclude an amended ANDA from its broadly worded final judgment. And it did so in part because Norwich had *not* done during trial what the defendant *had* done in *Ferring B.V.*

III. Conclusion

The Delaware District Court's final judgment means what the FDA understood it to mean — and what Norwich understood it to mean when it was issued: Norwich's '369 ANDA, whether amended or not, may not be approved until Salix's infringed patents expire in October 2029.

The FDA therefore did not act arbitrarily, capriciously, or otherwise contrary to law by delaying final approval of Norwich's amended '369 ANDA until October 2029.

We affirm.

So ordered.