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D.C. Circuit Clarifies Standards for 180-Day Forfeiture Decisions

In Norwich Pharmaceuticals, Inc. v. Kennedy, decided Aug. 25, the D.C. Circuit held that a first abbreviated new drug application (ANDA) applicant does not forfeit its 180-day exclusivity for failing to obtain timely tentative approval only if a change in, or review of, the approval requirements by the Food and Drug Administration (FDA) was a but-for cause of that failure. This is a rejection of FDA's long-held position that such a change need only be one of multiple sufficient causes of the failure to obtain timely tentative approval. In the same case, the court also affirmed FDA's position that each Paragraph IV certification in a first applicant's ANDA is what counts toward a "failure to market" forfeiture, regardless of how a later applicant certified.

Key Takeaways

- **"Caused by" means but-for causation.** The exception in 21 U.S.C. § 355(j)(5)(D)(i)(IV) — which spares a first filer that misses the 30-month tentative-approval deadline when the failure "is caused by a change in or a review of the requirements for approval" — incorporates the ordinary but-for causation standard. The court rejected FDA's application of a "multiple sufficient causes" test, under which an FDA review-related change need only be "one of the causes."
- **An ANDA that would have missed the deadline anyway gets no exception.** Under FDA's "multiple sufficient causes" test, a first filer with an independently disqualifying deficiency would keep its exclusivity if FDA happened to revise an unrelated requirement before the deadline. The court rejected that result: "there is no reason to think Congress intended to grant deficient ANDAs that kind of windfall."
- **FDA practice and administrative burden did not save the standard.** FDA defended the "multiple sufficient causes" test as its "longstanding" practice and warned that a but-for analysis would be difficult to conduct. Applying *Loper Bright*, the court gave no deference: FDA's "technical subject matter expertise" has "little to do with" the interpretation of a statutory term like "caused by."
- **The first filer's Paragraph IV certifications are what count for the failure-to-market forfeiture provision.** Under the "failure to market" provision, a triggering event must occur as to *each* Paragraph IV certification contained in the first filer's ANDA. That includes Paragraph IV certifications to patents that a later applicant elects to carve out under section viii, or that were never certified to at all.

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- **There is no partial forfeiture.** Under the statute, the first filer forfeits "[t]he 180-day exclusivity period" as to all subsequent applicants or none. A first filer cannot forfeit exclusivity against one later filer, while retaining the exclusivity against other later filers, because no statutory provision creates that mechanism.
- **The case is not over.** The court partially remanded the case and instructed FDA to run the but-for analysis with respect to the tentative-approval forfeiture issues, expressly leaving open whether some change or review *other* than the one FDA relied on was a but-for cause.

Background: How the Dispute Reached the D.C. Circuit

Salix Pharmaceuticals markets rifaximin as Xifaxan®. The 550 mg dosage strength of the drug treats irritable bowel syndrome with diarrhea (IBS-D) and hepatic encephalopathy (HE); the 200 mg dosage strength treats travelers' diarrhea.

On Dec. 18, 2015, Actavis Laboratories FL, Inc., a wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc., submitted the first ANDA for the 550 mg dosage strength of rifaximin. Actavis's ANDA included Paragraph IV certifications to Orange Book-listed patents covering the drug itself and its use for treating IBS-D and HE. Salix sued Actavis in March 2016 under the Hatch-Waxman framework, asserting various Orange Book patents that Actavis submitted Paragraph IV certifications against.

In March 2017, FDA published a revised draft of its product-specific guidance for rifaximin ANDAs, recommending additional dissolution studies to demonstrate bioequivalence. In September 2018, Salix and Actavis settled their Hatch-Waxman litigation on terms that allowed Actavis to market its rifaximin ANDA product no earlier than Jan. 1, 2028 — more than 22 months before the last Salix patent expires. FDA did not grant approval to Actavis's ANDA until March 19, roughly nine years after the ANDA was filed and long past Actavis's statutory 30-month deadline to obtain tentative approval for purposes of 180-day exclusivity.

Meanwhile, Norwich Pharmaceuticals submitted its own rifaximin ANDAs, including ANDA No. 214370, which was later amended to include the 550 mg strength. Norwich's ANDA included Paragraph IV certifications to the drug-substance and IBS-D patents that Actavis previously submitted Paragraph IV certifications against. However, while Actavis submitted a Paragraph IV certification against the Orange Book-listed patent covering the treatment of HE, Norwich elected to submit a section viii carve-out against that same HE patent. In January 2025, FDA concluded that Norwich's 550 mg product met the requirements for approval, but only granted *tentative* approval, pending Actavis's 180-day exclusivity.

Norwich sued FDA under the Administrative Procedure Act (APA) in the U.S. District Court for the District of Columbia, arguing that Actavis had forfeited its 180-day exclusivity twice over: first, by failing to market, and second, by failing to obtain timely tentative approval. The district court rejected both theories and granted summary judgment to FDA, Salix and Teva. On appeal, Judge Garcia, joined by Judges Pillard and Walker, affirmed on the first theory and reversed and remanded on the second.

The Failure-to-Market Holding: Assess Forfeiture from the First Applicant's Certifications

Under the failure-to-market provision, a first filer forfeits its 180-day exclusivity only once a triggering event — typically a final decision of invalidity or non-infringement — has occurred "as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period."[1]

Norwich argued that because its ANDA carved out the HE indication and patent under section viii, rather than submitting a Paragraph IV certification, Actavis's Paragraph IV certification to that patent was not a "qualifying" certification *against Norwich*. According to Norwich, triggering events had occurred for every patent that *both* Actavis and Norwich submitted Paragraph IV certifications against. Under Norwich's reading, Actavis had forfeited its exclusivity with respect to Norwich even though the HE patent was not invalidated or found not to be infringed.

The court rejected Norwich's argument based on the structure of statute, which grants a single exclusivity period that is "forfeited by a first applicant" when a forfeiture event occurs "with respect to that first applicant."[2] According to the court, nothing in the statute supports that a first applicant may forfeit exclusivity as to one subsequent applicant (*i.e.*, an applicant that submits a section viii carve out instead of a Paragraph IV certification) while keeping it as to other later applicants (*i.e.*, an applicant that submits the same certifications as the first applicant).

Moreover, the court explained that the forfeiture provisions as a whole look to the first applicant's ANDA, not to the certification strategy of later filers. Because a single Paragraph IV certification is all it takes to make an applicant a "first applicant," each Paragraph IV certification contained and lawfully maintained in that ANDA is a qualifying certification. Thus, the court held that Actavis has not forfeited exclusivity for failure to market, because no triggering event has occurred as to the HE patent.

The Tentative-Approval Holding: But-For Causation is Required

Under the tentative-approval forfeiture provision, a first filer forfeits its 180-day exclusivity if it "fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is *caused by* a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed."[3]

Here, Actavis submitted its ANDA on Dec. 18, 2015. To be eligible for the 180-day exclusivity, Actavis was required to obtain tentative approval by June 18, 2018. Actavis fell well-short of that 2018 deadline, only obtaining FDA approval on March 19.

However, in March 2017, FDA published a revised draft product-specific guidance for rifaximin that likely required Actavis to submit additional testing — testing that was not required when the ANDA was initially submitted in 2015 — to gain FDA approval. The FDA found the March 2017 product-specific guidance to be "one of the causes" of Actavis's failure to obtain tentative approval by the June 2018 deadline. Under FDA's "multiple sufficient causes" test, that was enough for Actavis to preserve its 180-day exclusivity under the forfeiture provision.

The court disagreed, instead holding that but-for causation is "part of the common understanding of cause" and one of the background principles against which Congress legislates. Courts read similar phrases — "results from," "because of," "based on," "by reason of" — the same way, and they depart from that default only on a textual or contextual indication.

Here, the court held that the statutory text did not call for departure. Missing the 30-month deadline forfeits exclusivity, and a but-for rule excuses the applicant only if it would have obtained tentative approval on time absent the FDA change. The court's analysis reflected application of the recent *Loper Bright* standard: courts do not defer to agency statutory interpretations, the panel noted, "particularly where, as with 'caused by,' the agency's

'technical subject matter expertise' has 'little to do with' the term in need of clarification."

Thus, the circuit court reversed the district court's and FDA's rejection of Norwich's arguments under the "failure to obtain tentative approval" provision because they applied the wrong causation standard. The court also remanded that issue to the district court "with instructions to remand to the FDA so that the agency may apply the but-for causation standard" to the facts of the case.

Implications of the *Norwich* Decision to First and Later ANDA Filers

ANDA applicants should carefully review the court's holdings with respect to both the failure-to-market and tentative approval forfeiture provisions because both holdings have a significant impact on ANDA certification and regulatory strategies.

The failure-to-market holding is critical for both first and later filers' certification strategies. A section viii carve-out, or a Paragraph III certification, does not narrow the set of patents that must clear before the first applicant forfeits its exclusivity, possibly incentivizing first-filers to submit Paragraph IV certifications against *all* Orange Book-listed patents in certain situations. On the flipside, a later filer may need to match at least the Paragraph IV certifications of the first filer to ensure the failure-to-market provision is triggered to ensure the first filer's exclusivity is forfeited. For example, a later filer that carves out a patent still has to wait for a triggering event on that patent if the first filer submitted a Paragraph IV certification to that same carved-out patent.

Further, the tentative-approval forfeiture provision now requires a more stringent but-for causation test. That new but-for causation test opens the door to more possible forfeitures if the first filer fails to obtain tentative approval within 30 months of submitting its ANDA. A first filer that has been sitting on exclusivity behind a missed 30-month deadline can no longer point to any contemporaneous FDA requirements change as a sufficient excuse, unless it is the *only* cause of the delayed approval. Any non-forfeiture determination that rested on a change being merely one contributing cause now rests on a standard the D.C. Circuit has rejected. The court's decision also leaves unanswered whether FDA changing several requirements at once, may in the aggregate be combined to constitute a but-for cause.

For more information on Hatch-Waxman exclusivity, ANDA forfeiture issues and related regulatory strategy considerations for generic drug applicants, contact the alert authors or your preferred Polsinelli attorney.

[1] 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)

[2] 21 U.S.C. § 355(j)(5)(D)(ii)–(iii)

[3] 21 U.S.C. § 355(j)(5)(D)(i)(IV) (emphasis added)