

## 10-844 CARACO PHARMACEUTICAL V. NOVO NORDISK A/S

DECISION BELOW: 601 F.3d 1359

LOWER COURT CASE NUMBER: 2010-1001

### QUESTION PRESENTED:

When the Food & Drug Administration (FDA) approves a drug for multiple uses, the Hatch-Waxman Act allows generic drug makers to avoid contested patent litigation by marketing generic versions of the drug solely for non-patented uses. The FDA lacks the authority and expertise needed to verify the patent information submitted by name-brand drug companies, however, so it defers to their descriptions of the scope of their patents. Such companies can therefore block the approval of generic drugs by submitting overbroad patent descriptions to the FDA, effectively extending their patents to cover non-infringing uses.

To combat this problem, the Act allows a "counterclaim seeking an order requiring the [patent] holder to correct or delete the patent information submitted by the holder \* \* \* on the ground that the patent does not claim \* \* \* an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I). In a 2-1 decision that conflicts with this Court's precedents and recent D.C. Circuit authority, the Federal Circuit held that the counterclaim provision effectively authorizes only "delet[ing]" improperly listed patents, but not "correct[ing]" information that misrepresents the scope of the approved uses claimed by a patent. That ruling expressly invalidates longstanding FDA regulations defining "patent information," which the FDA deems "essential" to administering the Act, without seeking the agency's views. The question presented is:

Whether this counterclaim provision applies where (1) there is "an approved method of using the drug" that "the patent does not claim," and (2) the brand submits "patent information" to the FDA that misstates the patent's scope, requiring "correct[ion]."

CERT. GRANTED 6/27/2011