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No Written Description for Claim to Species Based on Generic Disclosure Says the Federal Circuit

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In *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 2012-1433 (Fed. Cir. July 22, 2013), the Federal Circuit affirmed the district court's grant of DuPont's post-trial motion for judgment as a matter of law holding that Novozymes' U.S. Patent No. 7,713,723 ("the '723 patent"), directed to a variant of alpha-amylase, was invalid under 35 U.S.C. § 112, first paragraph, for failing to satisfy the written description requirement.[2] (Slip op. at 18). The Federal Circuit held that a generalized disclosure in the priority application of possible mutations that could be made to alpha-amylase so as to provide the variant is insufficient written description to support a claim to a species, *i.e.*, a specific variant, when there is nothing in the specification "that would lead an ordinary skilled investigator toward such a species among a slew of competing possibilities." (*Id.* at 24).

The claims of the '723 patent were directed to variants of alpha-amylase that had superior stability to heat and acid. The Federal Circuit noted that each of the claims of the '723 patent required an alpha-amylase variant with at least the following three features: (1) a parent sequence with at least 90 percent homology with BSG alpha amylase; (2) a substitution at position S239; and (3) increased thermostability determined at 90° C, pH 4.5, and 5 ppm calcium. (*Id.* at 10). The Federal Circuit acknowledged that the priority application (*i.e.*, "the 2000 application") "expressly stated" each of the three features required by the claims of the '723 patent, but found this insufficient to satisfy the written description requirement because:

> While the 2000 application provides formal textual support for each individual limitation recited in the claims of the '723 patent, it nowhere describes the actual functioning, thermostable alpha-amylase variants that those limitations together define. Taking each claim—as we must—as an integrated whole rather than as a collection of independent limitations, one searches the 2000 application in vain for the disclosure of even a single species that falls within the claims or for any "blaze marks" that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities.

(*Id.* at 24 citing *In re Ruschig*, 379 F.2d 990, 995 (CCPA 1967)). According to the Federal Circuit, the 2000 application only provided generalized guidance as to what variables might lead to a thermostable enzyme and that such a generalized disclosure did not show that patentees, at the time of filing the application, were in possession of the narrowly claimed species.

The Federal Circuit further reasoned that it is improper to work backward "from a knowledge of the claims, that is by hindsight, to derive written description support from an amalgam of disclosures plucked

selectively from the 2000 application." (*Id.*). Rather, the Federal Circuit held that the "proper vantage point" for viewing the claims is "one with no foreknowledge of the specific compound." (*Id.* at 25). When viewed from this vantage point, "one of ordinary skill in the art reading the 2000 application would have understood that Novozymes had only predicted that at least some mutations at position 239 would yield variants with increased thermostability, not that it possessed or had definitively identified any mutations that would do so." (*Id.* at 26). The Federal Circuit expressly rejected Novozymes' argument that the specification directed a person of ordinary skill in the art to modify position 239 and that they "would have known how to test every possible variant at that position and thus would have found the claimed variants as a matter of course" because it "misses the point." According to the Federal Circuit:

> To actually possess the variant enzymes claimed in the '723 patent would have required Novozymes to confirm its predictions by actually making and testing individual variants or at least identifying subclasses of variants that could be expected to possess the claimed properties, which it did not do before filing the 2000 application. At best, the 2000 application describes a roadmap for producing candidate alpha-amylase variants and then determining which might exhibit enhanced thermostability. A patent, however, "is not a reward for the search, but compensation for its successful conclusion."

(*Id.* at 27, citations omitted).

Novozymes provides further support, post-*Ariad,* for arguing written description as an independent requirement that does not include consideration of factors in an enablement analysis. Patent practitioners should be cognizant of this when attempting to rely on a broad genus disclosure to support a claim to an undisclosed species. Likewise, litigators should carefully scrutinize whether a priority application truly supports a claim to a narrow species when litigating such patents. With *Novozymes*, and the recent *Wyeth* decision finding lack of enablement for excessive experimentation, the Federal Circuit has given Section 112 more bite.

If you have any questions regarding these matters, please contact:

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[2] A "variant" is an enzyme that has one or more mutations (*i.e.*, a deletion, insertion, or substitution of an amino acid) relative to its natural parent amino acid sequence. (Slip op. at 5).