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Reading Between the Lines: The Pitfalls of Repurposing Patent Applications

By David P. Halstead and Raymond M. Doss

Scientific research by its very nature constantly evolves. In the context of pharmaceutical and biotechnology research, this evolution is a slow and lengthy process driven by myriad factors ranging from new discoveries in basic research to regulatory requirements. This unpredictable process challenges patent applicants trying to protect the full breadth of research, especially in the early stages of development. Patent applicants often ''hedge their bets'' in early filings — such as provisional applications — by describing their inventions in sweeping statements and cataloging every conceivable product and use in an effort to capture current and future research as well as potential commercial products and services. Some applicants carefully refine their early filings before filing non-provisional applications by, for example, adding specific description of experiments conducted after filing the initial application. Often, though, the evolutionary process leaves applicants relying on broad, general disclosures in their earlier applications as support for both broad and narrow claims, hoping to reshape these disclosures to cover later developments, even those invented long after the application was filed.

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R&D Discoveries May Pave Tricky Path

This path is a tricky one, because the course of research and development—yours or your competitors'—may veer outside the scope of earlier patent filings. One recent Federal Circuit decision shows how this can happen even where the technology at issue appeared to be still within the scope of earlier filings. In *Novozymes v. DuPont*, the U.S. Court of Appeals for the Federal Circuit found Novozymes' claims to alpha-amylase variants (enzyme variants) in U.S. Patent No. 7,713,723 (''the '723 patent'') invalid for failing to satisfy the written description requirement—even though the claim language was present in the specification of the patent and the provisional application to which it claimed priority.

The '723 patent claims were drawn to BSG (*B. stearothermophilus*) enzyme variants having properties including increased stability at high temperatures and low calcium concentrations. Such enzymes are useful in several commercial processes including the formulation of detergents, the refinement of sugar, and ethanol production. Novozymes filed the '723 patent claims in a continuation of an older application after learning that DuPont had developed an enzyme variant (mutated at amino acid position 239) that demonstrated some of these useful properties. All the claims of the '723 patent required an enzyme variant with at least the following three general features: (1) an amino acid sequence having at least 90 percent homology with the naturally occurring BSG enzyme; (2) a mutation at amino acid position 239; and (3) increased stability at 90°C, pH 4.5, and 5 parts per million calcium.

In its analysis, the court focused on the specification of Novozymes' provisional application. In doing so, the court noted that the provisional application disclosed (1) seven different enzymes, including BSG alpha-amylase; (2) 33 potential mutation positions, including the mutation at amino acid position 239; and (3) statements that the variants would exhibit improved stability at high temperatures and extreme pH. Though the provisional application disclosed specific, exemplary substitutions, it did not state which of the disclosed mutation sites were preferred, or that representative enzymes with the claimed mutation site were prepared and tested.

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Although the court agreed that *each of the three characteristics was expressly disclosed in the provisional application individually*, it expressed concern about combining all three together:

> While the [provisional] 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 [provisional] 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.

The court clearly stated that the written description requirement may not be satisfied by stitching together disparate portions of the specification to arrive at the claimed invention. A fair analogy may be made to proceedings before the European Patent Office (EPO), where Article 123(2) EPC prohibits the amendment of an application ''in such a way that it contains subject matter which extends beyond the content of the application as filed.'' While this might suggest merely that the applicant cannot claim *more broadly* than the scope of the original filing, the EPO has interpreted this article to require that the specification provide near *ipsis verbis* or literal support for the claimed invention — an issue that can plague narrow claims as well. Thus, claiming a combination of elements requires that the original disclosure clearly and unambiguously supports the combination of those elements in the same manner as in the claim.

The complicated facts of *Novozymes* make it difficult to predict how strictly the Federal Circuit intends to enforce the written description requirement. For example, the court specifically noted that the provisional application failed to describe an enzyme variant within the scope of the '723 patent claims — a failure of the type that doomed Ariad in *Ariad v. Lilly* (Fed. Cir. 2010). Had the provisional application disclosed an enzyme inherently falling within the scope of the claims (i.e., which by its nature satisfied all the claim elements), even without specifically ascribing all of the claimed properties to that enzyme, would the *Novozymes* court have ruled differently? No one wants to be the first to find out. But that type of situation—where the sole support for a combination of claim features is found only in a specific example—would not lend patentability to such a claim under the EPO's system. Only the specific example itself—nothing broader—would be patentable.

Though the court focused on the content of the provisional application in its analysis, the priority date was less the issue than simply whether or not the application supported the claims. Indeed, the court noted that the provisional application and the issued patent had nearly identical specifications. Typically, however, not only are there differences between a provisional and subsequent non-provisional applications, but the differences can be substantial. The right to a priority filing date can be critical to the patentability of a claim, especially in publish-or-perish academic environments or fiercely competitive technologies. One of the requirements of a proper priority claim is that the provisional application provide the requisite written description for the ultimately claimed invention. Accordingly, even where the specification of an issued patent properly describes the claimed invention, if the earlier-filed provisional application fails to provide adequate written description support, prior art arising between the provisional and non-provisional filings may undermine the claim. Filing broad and general provisional applications may fail to support narrow claims, just as narrow ''cover sheet'' provisionals often lack support for broad claims.

'First-to-File' Demands Adequate Written Description Support

The recent change in U.S. patent law — from the ''first-to-invent'' to the ''first-inventor-to-file'' system — redoubles the importance of ensuring that provisional applications contain adequate written description support. March 2013 saw a landslide of patent filings seeking examination under the older ''first-to-invent'' system, which offers more favorable ground for many patent applicants. Later applications that claim priority to first-to-invent applications also receive the benefit of the first-to-invent system—but only so long as every claim presented in the later application is supported in the first-to-invent priority document. *Novozymes* may be an early warning sign that presenting a claim to a specific embodiment that is not adequately supported in its priority document can cost the later application its first-to-invent status—and send it irrevocably into the first-to-file system. Similarly, the U.S.'s one-year grace period runs from the first application that adequately discloses the claimed invention. If the patentability of that application depends on swearing behind prior art or showing an earlier date of invention, then all is lost.

In *Novozymes*, the majority may have been troubled by what it considered to be the speculative disclosure of a plethora of possible alpha-amylase variants without either explicit disclosure of the claimed variant (with the three general features recited in the claim), or an indication that Novozymes had possessed—physically or even conceptually—a BSG alpha-amylase variant substituted at position 239 at the time the provisional application was filed. These concerns likely were amplified by the perception that Novozymes' claims were an awkward retrofit inspired by a competitor's research successes. In light of this holding, applicants should be vigilant in reviewing their patent filings to ensure that they cover the current state of research. Filing new applications covering the latest research developments is a more reliable alternative than creative claiming in established portfolios, especially in applications reliant on the inventor-friendly first-to-invent system. In instances where new filings are not a viable option, applicants should take steps to protect the first-to-invent status of existing portfolios by pursuing aggressive claims in applications that won't jeopardize the first-to-invent status of related applications.

The *Novozymes* holding casts a dark shadow into the pharmaceutical space as well. Organic molecules are often protected by broad Markush structures with many independently defined variable substituents. If prior art requires narrowing the scope of the claim, the specification may lack support for claims where two or more variables must be narrowed simultaneously. The EPO generally prohibits simultaneous narrowing of two or more variables—unless of course the specification ex-

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plicitly discloses the combination of narrowed features. Applicants can guard against these difficulties by conducting prior art searches so that applications and claims can be intelligently drafted with relevant prior art in mind. Because no search can uncover the last 18 months' worth of unpublished patent filings, care should be taken to draft narrowing embodiments that can support different types of claim amendments. Finally, applicants should include embodiments more narrowly tailored to compounds of interest not only to support strong claims to protect the applicant's product, but also to support claims that may sweep in competitor products.

Conclusion

Novozymes may turn out to be an aberration in the U.S., or it may not. But the holding of *Novozymes* is representative of certain foreign patent systems—the patent systems of jurisdictions whose economic importance is growing. Aberration or not, *Novozymes* should warn U.S. applicants of the importance of careful drafting, both of the original application and of the claims that constantly evolve with the science, the product and the competition.