MARCH/APRIL 2021
VOLUME 27 NUMBER 2

IP Litigator®

DEVOTED TO INTELLECTUAL PROPERTY LITIGATION & ENFORCEMENT

Edited by Gregory J. Battersby and Charles W. Grimes

FEATURES

COLUMNS

Wolters Kluwer

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Don't Be Caught without Possession (of Your Invention): What You Need To Know about the Written Description Requirement

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Introduction

The written description requirement under US patent law seeks to incentivize "actual invention" as opposed to "attempts to preempt the future before it has arrived." *Ariad Pharmaceuticals Inc. v. Eli Lilly & Co. 598 F.3d 1336, 1353 (Fed. Cir. 2010)*. How this policy is implemented is an important factor in defining the strength and scope of the exclusivity afforded by a patent grant. It has been just over ten years since the Federal Circuit reaffirmed that there is a written description requirement separate and distinct from the requirement that the invention be enabled. Two recent cases before the Federal Circuit illustrate the ongoing development of written description jurisprudence in the US since *Ariad*. This article reviews these cases and a few older post-*Ariad* cases to illustrate what may be a trend in how the written description requirement is developing in the pharmaceutical and biotechnology related arts, particularly as applied to genus claims covering molecules large and small, including antibodies, enzymes, and small organic molecules. An important takeaway is that genus claims, especially those employing functional language, may be increasingly susceptible to an invalidity attack based on lack of written description, as well as enablement, to the extent this line of cases is followed. Since these types of claims may also be the most valuable, it is important for stakeholders to understand these developments and their implications. This is also a critical issue beyond the United States, where some of the most desirable markets are located in jurisdictions that tend to interpret the written description requirement more strictly than in the US, at least outside of the 'blaze marks' line of cases discussed here.

Part I: Blazing a Trail through the Written Description Forest: *Novozymes* and *Idenix*

Most stakeholders will be aware of the requirement under US law to provide a "written description of the invention, and of the manner and process of making and using it" under 35 U.S.C. § 112 (a). Some may have heard about "blaze marks" and the perils of "functional" claiming. Yet written description is often not as appreciated or understood as other patentability requirements such as enablement, novelty, and non-obviousness. One reason may be that the Federal Circuit in *Ariad* eschewed laying down any bright-line rules as to what is required to satisfy written description. What we know from *Ariad* is that describing "groundbreaking research" in itself is not enough. The court explained that "[a] patent is not a hunting license" or "a reward for the search"; rather,

it is "compensation for a successful conclusion." *Ariad, 598 F.3d at 1353*. Indeed, a research plan without more is insufficient, although neither specific examples nor an actual reduction to practice is strictly required. Instead, "a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement." *Id.* at 1352. Yet, "actual 'possession' or reduction to practice outside of the specification is [also] not enough." *Id.* Instead, "the specification itself must demonstrate possession." *Id*. And, while the specification need not recite the claimed invention *in haec verba*, "a description that merely renders the invention obvious does not satisfy the requirement". *Id*.

Problems with both written description and enablement most commonly arise in the context of claims covering a genus broader than the examples provided in the patent specification. The same breadth that makes these claims highly desirable from an enforcement perspective renders them susceptible to invalidity attack. With respect to written description, the legal standard is generally characterized as requiring that the specification describe "a representative number of species" of the genus, or a set of common structural features shared by the members of the genus such that the person of ordinary skill would recognize each and every species of the claimed genus. *Ariad*, 598 F.3d at 1350. Satisfying this fact-specific requirement can be particularly difficult in chemical cases, where the specification may disclose a large genus of possible compounds. Yet, if it does not somehow guide the skilled person to the particular compound at issue encompassed by the claim, sufficient written description may be found lacking. *Id.* at 1347 (discussing *In re Ruschig*, 379 F.2d 990, 994–95 (CCPA 1967) and the importance of the claimed invention appearing in the specification). In an early post-*Ariad* case, the Federal Circuit found a genus claim to enzyme variants invalid because the specification failed to "provide sufficient 'blaze marks' to guide a reader through the forest of disclosed possibilities" toward the claimed compound at issue encompassed by the genus. *Novozymes A/S v. DuPont Nutrition Biosciences APS,* 723 F.3d 1336, 1346 (Fed. Cir. 2013), *cert denied* 571 U.S. 1244 (2014) (quoting *In re Ruschig*). The "blaze marks" rule announced by *Ruschig* was also discussed in *Ariad* and raised again more recently in *Idenix.* But what are "blaze marks" and when are they required?

Novozymes' patent claimed genetic variants of alpha-amylase enzymes at position 239 of the amino acid sequence of a parent protein that conferred increased resistance to high heat and acidity. *Novozymes* 723 F.3d at 1339. The specification identified 33 potential mutation sites in the alpha-amylase protein along with seven potential corresponding parent enzymes that could be altered by any of a deletion, addition, or substitution in one or more of those sites to obtain variants with improved stability. *Id* at 1340. The specification further included pages of exemplary variants, in single, double, triple, and larger combinations. The original application was filed in 2000 and contained two specific examples of enzyme variants with improved properties. Meanwhile, DuPont was developing its own enzyme variants and received a patent in June 2009 based on a specific variant having a substitution at amino acid position 239 that replaced serine with glutamine (S239Q). Although position 239 was one of the mutation sites identified in the Novozymes' application, the corresponding specification did not describe a substitution resulting in glutamine (Q). Instead, each of the 17 embodiments with a specific substitution at this position replaced the original serine with the amino acid tryptophan (S239W). In December 2009, Novozymes filed a new continuation application specifically claiming enzyme variants at position 239 and received US 7,713,723 (the '723 patent) in 2010, which was the patent asserted in the district court. Based on all of these facts, a divided three-judge panel of the Federal Circuit affirmed the district court's grant of a post-trial motion for judgment as a matter of law holding Novozymes' patent invalid for failing to satisfy the written description requirement. *Id* at 1346. The district court decision as affirmed by the Federal Circuit nullified an award of more than $18 million in damages to Novozymes after the jury determined that the '723 patent's claims were not invalid on enablement or written description grounds. Notwithstanding the jury's conclusion and the fact that each and every element of the claims was expressly recited in the specification, the district court entered judgment in favor of DuPont. In its decision affirming the district court, the Federal Circuit remarked that

> In contrast to the claims—which narrowly recite specific alpha-amylase variants that result from mutating a particular parent enzyme at a single amino acid position to yield distinctive functional properties—the supporting disclosure of the 2000 application provides only generalized guidance listing several variables that might, in some combination, lead to a useful result. *Taking the claims as a whole rather than as the sum of their individual limitations*, nothing in the 2000 application indicates that Novozymes then possessed what it now claims.

723 F.3d 1336, 1345 (emphasis added).

Despite an extensive listing of possible enzyme variants, what the court found missing from the specification in *Novozymes* was some indication that the combination of features now claimed, namely variants obtained by mutating position 239 of a particular parent enzyme, was known at the time of filing. Instead, the court found that

the '723 patent contained "no disclosure of any variant that actually satisfies the claims, nor . . . anything to suggest that Novozymes actually possessed such a variant at the time of filing." 723 F.3d at 1348. Since this case was decided in 2013 it has been cited for the proposition that "the written description requirement prohibits a patentee from leaving it to the . . . industry to complete an unfinished invention." *Id.* at 1350 (internal quotations and citations omitted).

More recently, the Federal Circuit, in *Idenix Pharm. LLC v. Gilead Scis. Inc.*, again invoked *In re Ruschig* in characterizing the written description inquiry as "looking for blaze marks which single out particular trees" in a forest, rather than simply "pointing to trees", and held a patent invalid in part for failing to provide such blaze marks. 941 F.3d 1149 (Fed. Cir. 2019) *cert denied* 2021 U.S. LEXIS 620 (2021). At issue in *Idenix* was a genus claim directed to methods of treating hepatitis C by administering nucleoside compounds of a defined structure. It was undisputed that the claims encompassed Gilead's HCV therapeutic, sofosbuvir. The claim at issue was directed to nucleosides "having a methyl substitution (CH3) at the 2'-up position of the molecule's sugar ring." 941 F.3d at 1154. Idenix argued that this feature was the key inventive aspect of the genus of molecules encompassed by the claim. Gilead's compound had a fluorine (F) at the 2'-down position, for which the claim did not specify any particular substitution.

The parties' arguments focused on the number of possible compounds encompassed by the variable 2'-up and 2'-down positions. *Idenix*, 941 F.3d. at 1154. In its arguments in defense of enablement, Idenix's counsel conceded that the structural limitations of the claimed genus encompass "some number of thousands" of compounds. Yet, with respect to written description, Idenix argued that the specification provides "abundant traditional blazemarks for the claims—working examples, formulas, data, synthesis routes, and the target." But the court found that "[e]ach of these suffer from the same flaw" which was that they provided merely "lists or examples of supposedly effective nucleosides" while failing to "explain what makes them effective, or why." *Id.* at 1164. According to the majority, the result was to deprive the skilled person "of any meaningful guidance into what compounds beyond the examples and formulas, if any, would provide the same result." *Id*. The sheer number of disclosed compounds, "tens or hundreds of thousands of possible nucleosides", also seems to have undermined Idenix's 'blazemarks' position. The court also took notice that among the many thousands of possible compounds, "the compound in question is conspicuously absent." *Id.* at 1165. While all seven chemical formulas listed fluorine as a possibility at other positions, including the 2'-up position, and the formulas also included every other halogen at both the 2'-up and 2'-down positions, none specified fluorine at the 2'-down position, as it was in Gilead's accused compound. The court dismissed the possibility that the skilled person would have nevertheless envisioned fluorine at the 2'-down position based on its similarity with other halogens because "[a] description that merely renders the invention obvious does not satisfy the written description requirement." *Id.* (*quoting Ariad*, 598 F.3d at 1352).

It is worth taking note that based on these precedents, a genus claim may be susceptible to an invalidity attack where the specification lacks "meaningful guidance" or "blaze marks" leading to each of the species encompassed by the claimed genus. This is consistent with the rule followed by the US Patent and Trademark Office during examination of applications providing that while a species anticipates a genus, a genus does not necessarily anticipate the species. In addition, although including extensive 'lists' of various claim elements in the specification is a common practice and often relied upon as support for later drafting a claim having any combination of the listed elements, this approach does not necessarily provide adequate written description for the later-claimed combination.

Part II: Written Description and Functional Claiming

When the Federal Circuit confirmed the existence of a written description requirement as separate and distinct from enablement in *Ariad* more than ten years ago, the court acknowledged that in some cases, there may be little difference between the two. *See Ariad*, 598 F.3d at 1352. However, the court also envisioned cases where the claims at issue may not require undue experimentation to make and use, and thus may be enabled, "*but have not been invented, and thus cannot be described*." *Id.* (emphasis added). The court saw this as a particularly important issue for biotechnology patents, where a product, such as an antibody, may be claimed by its function or result. In those instances, the court noted that the specification must recite "sufficient materials to accomplish that function." *Id.* at 1353.

That issue of sufficiency was presented in the course of ongoing *Amgen v. Sanofi* litigation involving functionally claimed antibodies, and in which the Federal Circuit recently issued a second opinion following a second district court jury trial. Amgen's asserted claims are directed to anti-PCSK9 antibodies that bind to "at least one" of 15 listed amino acids of PCSK9 and block its binding to the low density lipoprotein receptor (LDLR). The claims cover Amgen's Repatha™ and Sanofi/Regeneron

stipulated to infringement of selected claims with respect to its accused product, Praluent™, while continuing to litigate validity. In the first trial, a jury found the patents were not invalid for lack of enablement and written description based on the district court's instruction that:

> In the case of a claim to antibodies, the correlation between structure and function may also be satisfied by the disclosure of a newly characterized antigen by its structure, formula, chemical name, or physical properties if you find that the level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against such an antigen was conventional or routine.

Amgen Inc. v. Sanofi, 872 F.3d 1367, 1376 (Fed. Cir. 2017). The Federal Circuit reversed and repudiated this "newly characterized antigen" test for written description of an antibody as flouting the "basic legal principles of the written description requirement." *Id.* at 1378. That test would have allowed the written description of an antibody to be satisfied by the disclosure of a newly characterized antigen. The rationale was that the correlation between an antibody's structure and its ability to bind a particular antigen would satisfy the "common structural features" prong of the written description requirement. Rejecting this approach, the Federal Circuit explained that the art failed to establish a correlation such that knowledge of the antigen provides the necessary structure-identifying information about the corresponding antibodies. While noting that this had been a hotly contested issue in the case, the court determined that the ease by which antibodies are generated was irrelevant to the written description inquiry. *Id*.

After a new trial where the jury again held the challenged patent claims valid, the district court granted Sanofi's motion for judgment as a matter of law on enablement, but denied a second motion contending that the claims were invalid for a lack of written description. On appeal to the Federal Circuit for the second time, Amgen challenged the district court's determination that the claims were not enabled, while Sanofi, *inter alia*, argued that the claims were not enabled and also failed the test for written description. The patent specification at issue is 384 pages long and includes numerous examples, including one describing the generation of hundreds of blocking antibodies. It also includes complementarity determining region (CDR) sequences for 26 antibodies as well as crystal structures of two showing binding to PCSK9. In its brief, Sanofi contended that these 26 specific antibodies were not 'representative' of the entire claimed genus because they failed to reflect the diversity of possible combinations for binding to the specific amino acids recited in the claim. Sanofi also argued that there was a lack of structural similarity, either at the amino acid sequence level, or in the three-dimensional structure of the antibodies. Amgen countered that there is no correlation between the number of amino acids bound and the ability of an antibody to block binding to LDLR. Amgen went on to argue that binding even one of the specified amino acids would be enough to fulfill the claimed function.

In a precedential opinion issued February 11, 2021, the Federal Circuit affirmed the district court decision and held Amgen's claims invalid for lack of enablement, without addressing written description. The opinion emphasized the breadth of the functional requirements of the composition claims, explaining that the undue experimentation inquiry includes a consideration of the experimentation necessary to identify the compounds that meet the functional requirements from among "the many concretely identified compounds that meet the structural requirements". Slip Op. at 11 (quoting from a footnote in *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091 (Fed. Cir. 2020)). Agreeing with the district court that the specification did not enable the full scope of the claims, the Federal Circuit noted that the claims at issue were "indisputably broad", the concern being not "simply with the number of embodiments but also with their *functional* breadth." Slip Op. at 11–12. (emphasis in the original). In the court's view, the claims were "far broader in functional diversity than the disclosed examples." Slip Op. at 12. The Federal Circuit also agreed with the district court that the invention was in "an unpredictable field of science with respect to satisfying the full scope of the functional limitations." *Id*. In view of this unpredictability, the "roadmap" for producing antibodies described in the specification was deemed insufficient guidance beyond the comparatively narrow scope of the working examples. Slip Op. at 13.

Although the court's opinion in *Amgen* rested on lack of enablement, it seems reasonable to expect that where "the use of broad functional claim limitations raises the bar for enablement" (Slip Op. at 12) it will also raise the bar for written description. Although the written description issue was not dispositive of validity in *Amgen*, for unpredictable technologies, where the claims must rely on functional language to define a genus of compounds, it would be prudent to include at least one specific example representative of each species falling within the genus, in addition to methods for producing the full scope of compounds having the specified structural and functional elements.

In summary, these cases illustrate what may become a trend toward a higher bar for satisfying the written description requirement in unpredictable arts, which generally include the pharmaceutical and biotechnology

arts. For genus claims, satisfaction of the written description requirement may be found lacking where the specification fails to provide "meaningful guidance" or "blaze marks" pointing to a number of species representative of the entire scope of the claimed genus. Where the claim further relies upon functional language to define a genus of compounds, that bar is likely to be higher. In such cases, it would be prudent to include a number of specific examples of species that are representative across the entire scope of the claimed structural and functional elements. It is also important to keep in mind that sufficient written description must be present in the application as-filed, it cannot later be added without a loss of the filing date. So patentees and their counsel should consider the issues surrounding written description early, and preferably within the context of a comprehensive patent strategy for the technology involved.