“Written description” as a patentability requirement has recently been pushed into the limelight by a debate among the judges of the Federal Circuit. One camp led by Judge Rader believes that the written description requirement has been and should remain in its traditional role as “a doctrine to prevent applicants from adding new inventions to an older disclosure.” Judge Rader further stated that it is “superfluous and dangerous” to have written description as a distinct and separate patentability requirement in addition to the enablement requirement.

On the other hand, several judges led by Judge Lourie believe that written description is a separate and distinct requirement for patentability and can be used as a separate basis for invalidation. Judge Lourie has argued that even if the “written description [requirement] has only been relied upon in recent years as a ground of invalidity [it] does not remove that requirement from the statute.” Nonetheless, with its recent decisions including the University of Rochester and its denial of en banc review of that case, the Federal Circuit has entrenched “written description” as a separate and distinct requirement for patentability that is applicable to all claims, and that is applicable to all technologies and not limited to biotech inventions only.

This recent heightened attention to the written description requirement has significant implications for patenting inventions from early stage research, and could significantly affect how researchers who discover new biochemical targets and techniques can protect and capitalize on their discoveries. Patentees, patent prosecutors, and patent litigators involved in early stage research need to understand what does and does not satisfy the written description requirement, and how it can affect their intellectual property protection strategy. The written description requirement originates in Section 112 of the patent statute which states, “the specification shall contain a written description of the invention, and of the manner and process of making and using it….”

The Federal Circuit in Enzo found that the written description requirement is to serve as a “quid pro quo,” in which the public is given “meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.” “To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.”

One source of guidance on meeting the written description requirement is the PTO Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112 ¶1. “Written Description” Requirement, which are available online at http://www.uspto.gov/web/offices/com/sol/notices/writdesguide.pdf. These guidelines became effective on January 5, 2001 and are applicable to all technologies. The guidelines say that written description can be satisfied by:

1. description of an actual reduction to practice of the claimed invention,
2. reduction to drawings or chemical formulas, or
3. description in terms of distinguishing characteristics sufficiently detailed to show that the inventor was in possession of the claimed invention. Claims to a genus must be supported by “sufficient description of a representative number of species” within the genus. To reject a claim during prosecution, the PTO must establish that a skilled practitioner of the art "would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure as filed." Recent decisions by the Federal Circuit also provide important guidance for the pharmaceutical and biotechnology industry on meeting the written description requirement. However, the Federal Court has also held that whether the written description requirement is satisfied is a question of fact rather than one of law, so “the precedential value of cases in this area is extremely limited.” Nevertheless, the cases discussed below address some issues that may be important to those involved in early stage research.
One particularly important issue to the early stage inventors in biotechnology and pharmaceutical arenas is whether functional information or incomplete structural information can satisfy the written description requirement. In some recent cases, the Federal Circuit indicates that functional language may not be sufficient in the absence of some connection that allows others to recognize the structure of a compound that is claimed or is essential to the invention.[11]

In Fiers, the court rejected an applicant's claims to a gene when only its principal biological property was described. [12] That Court held that “when an inventor is unable to envision the detailed chemical structure of the gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved.” Similarly, in Rochester, the court affirmed summary judgment of invalidity for failure to comply with the written description requirement for method claims requiring the use of a compound that is a selective COX-2 inhibitor. Because the specification did not identify any compound with the required selectivity, the Court found the claim lacked proper written description. A person of ordinary skill in the art would not have known of any compound having the required functional characteristics.[13] However, the Federal Circuit has indicated that functional descriptions of a material can, in some cases, meet the written description requirement if those functional characteristics are “coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.”[14] Antibodies, for example, may be adequately described by the antigens they recognize, and very recently the court has said that a protein may adequately describe the genus of DNAs encoding it based on the well-known genetic code and the current state of the art for obtaining such DNA sequences.[15]

Another important issue relates to how many species are needed to support a claim to a genus large enough to protect the invention from close copying. In addressing this issue, courts have considered the predictability or unpredictability of the art.[16] If the art is unpredictable, the disclosure of more species may be necessary to adequately show possession of the entire genus.[17] In Eli Lilly, one example of a cDNA did not support a broad genus claim, even though the patent disclosed methods for obtaining cDNA from other species. In Amgen v. Hoechst,[18] a few years later, the court said that two genetically modified cell types were sufficient description to support claims to a broad genus of mammalian or vertebrate cells. Thus written description to support a genus of chemical or biological materials probably requires multiple examples, but two may be enough, depending on the facts.

Another issue for biotech inventors is understanding what information is sufficient to describe a DNA that is claimed. The Fiers court in 1993 said a description required “a precise definition, such as by structure, formula, chemical name, or physical properties.” The Eli Lilly court in 1997 said, “[d]escribing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself.” But this year, in In re Wallach, the court found, “the state of the art has developed such that the complete amino acid sequence of a protein may put one in possession of the genus of DNA sequences encoding it.” Since the standard for written description is based on what the disclosure provided would convey to one of ordinary skill when the application was filed, the standard does adapt to track technological advances—though of course such pronouncements from the court may have no impact on patents filed years ago. The court in Wallach still held that possession of a protein and disclosure of a small part of its structure (10 amino acids of a 30 kD protein) along with some of its physical properties and biochemical activity were not sufficient to support claims to the DNA encoding the protein. Like the court in Rochester, the Wallach court thus held that the written description requirement prevents an inventor from patenting ‘the next step’ in the research progression. The inventor can claim only that which is described in the patent, and cannot ‘reach through’ a described invention to claim subject matter that is not adequately described.

The above cases suggest that disclosing a limited number of examples puts substantial discretion in the hands of the PTO or the courts to determine whether a genus is supported; the PTO or court will consider how predictable the particular technology was when the application was filed. Thus a patentee might aid his case for patentability by providing multiple examples. Chemical and biochemical claims seemingly must be connected to actual or at least prophetic structures to meet the PTO guidelines, although the connection to structure in antibody claims is usually to the structure of an antigen rather than to the claimed antibody. Claims to a genus of DNA or protein sequences seem to be adequately supported by a few examples, and now Wallach indicates that a protein sequence may provide written description for the genus of DNAs encoding it—but perhaps not for any single species in that genus. Finally, Enzo shows that a deposit of material into a public depository may provide adequate written description for the material actually deposited (the species) and for whatever additional structures (genus) it would convey to one of ordinary skill at the time.

In view of today's heightened scrutiny of the sufficiency of written description, universities and small companies engaging in early stage research may consider delaying filing for patent protection until they have the resources to make at least a few lead compounds if they are claiming compounds or methods to use such compounds. For claims to biological materials, they should consider waiting until they get structural information for or at least make a deposit of the biological material before filing
an application. If an applicant decides to claim an invention in functional terms, he should be aware that future Court decisions may diminish the value of any patent obtained.

The current written description law will impact patent prosecution and litigation for years to come. The opinions from the denial of en banc rehearing in Rochester show that many on the court want to address the written description requirement en banc to clarify the written description standards. It appears the court is waiting for the right case. Until then, prudent inventors will carefully time their applications to maximize the odds of satisfying the written description requirement.

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Notes:

2. Rochester II, 375 F.3d at 1307, denying en banc review, dissenting opinion of Judge Rader.
3. Id. at 1312.
4. Id. at 1306, concurring opinion of Judge Lourie.
8. Id. at 1106.
9. Id.