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# Client Alert

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## INTELLECTUAL PROPERTY

### U.S. Patent Court Rules on Deposit of Biological Organisms and the Written Description Requirement of the Patent Law

A recent case decided by the Court of Appeals for the Federal Circuit (CAFC), the highest specialized court of appeal for intellectual property law, appears to have raised the standards for obtaining patent protection for biological compositions. The case, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, No. 01-1230, decided April 2, 2002, has broad implications for biotechnology companies seeking to protect (and possibly enforce) their discoveries.

The deposit of biological materials with, *e.g.*, the American Type Culture Collection (ATCC), is a common practice for academic scientists and research institutions. These organizations store and distribute cell lines and other materials, making them available to other researchers throughout the world, in most instances for a nominal fee. By contrast, biotechnology companies, whose business models depend on preserving the proprietary nature of their innovations, tend to utilize depository organizations only when necessary, *e.g.*, to obtain patent protection.

The *Enzo* case appears to add a new wrinkle to biotech patent practice, one which you should take into consideration when not only applying for patent protection, but in the nature and amount of supporting research for the invention which you are seeking protection. *Enzo* holds that the deposit of biological materials, without additional description in the patent specification, does not necessarily satisfy the written description requirement for patentability imposed by 35 U.S.C. §112, ¶1. Accordingly, biotechnology companies and others seeking patent protection for biological materials, may not be able to rely purely on a deposit of the invention with a depository organization like the ATCC. Also, nucleic acids or proteins should include as thorough a description of those materials as possible in the patent specification. *Enzo*, and its implications for patent examination and enforceability are discussed below.

## Written Description

Title 35 of the United States Code, §112, ¶1, states that

“The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same...”

Compliance with the written description requirement is a fact-based inquiry that necessarily varies depending on the particular invention. It plays a crucial role in both the examination of patent applications and the enforceability of issued patents.

During examination, the claims of the application are reviewed solely on the basis of the description of the invention contained in the specification. A claim or claim element must be adequately described so that the Examiner can recognize what the subject matter of the claim is and use that to help determine the claim scope, and distinguish the claim(s) from the prior art. Stated another way, the written description informs the Examiner of what the applicant considers to be the invention.

The claim language must describe the invention so that one skilled in the relevant art can recognize what is claimed. The claims are thus interpreted by their written description in the patent specification, and provide notice to the public as to the limits of the patent. The written description requirement also ensures that the patent conveys to those skilled in

the relevant art that the inventor had possession of the invention as of the filing date of the patent application. However, as *Enzo* points out, if a patent shows possession of the claimed invention *without* providing an adequate written description of the invention, it may be held unenforceable.

Accordingly, if the written description is absent, vague, or otherwise unclear, it greatly complicates prosecution of the patent application, and also provides several points of attack against the validity of the issued patent. Thus an adequate written description of the claim elements is an essential part of both the application process, and the quality and enforceability of an issued patent.

## Depositing Biological Materials

Biological materials deposited for the purpose of obtaining a patent includes materials that are self-replicating, either directly or indirectly, for example, cells or cell lines, hybridomas, seeds, microorganisms, and the like. Viruses, plasmids or other vectors, organelles, or non-living materials, existing in, or reproducible from a living cell may also be deposited, by deposit of the host cell capable of reproducing the non-living material. Where an invention is (or relies on) biological material, the disclosure of a patent application may include reference to a deposit of the material, but that reference does not create the presumption that the deposit was either necessary or was required by the Patent Office.

The deposit of biological materials allows an interested party to practice an invention when a unique starting material is required. It provides a

sample of the invention, allowing the public access to the material, for example, to use when the patent expires, or for a use that does not otherwise infringe the claims of a valid patent. During the examination of a patent application, the Examiner determines if a deposit of biological materials is necessary.

Biological material does not need to be deposited if it is known or is readily available to the public, or can be made without undue experimentation.

## The Enzo Case

Enzo Biochem's U.S. Patent No. 4,900,659 (the "659 Patent") describes nucleotide sequence compositions and methods for screening for a nucleotide sequence specific for the pathogenic bacterium *Neisseria gonorrhoeae*. The 659 Patent describes fragments of chromosomal DNA (obtained from an isolated sample of *N. gonorrhoeae*) that preferentially hybridize to *N. gonorrhoeae* over other nonpathogenic *Neisseria* strains. The compositions and methods described in the 659 Patent thus allow for a user to detect chromosomal *N. gonorrhoeae* DNA, and thus the pathogenic organism.

These chromosomal fragments were described in terms of their sizes after restriction endonuclease digestion, but no specific sequence information was provided in the 659 Patent. Three of these chromosomal fragments were subcloned into M13 phage vectors, transformed into an *E. coli* host, and deposited with ATCC. Six strains of pathogenic *Neisseria gonorrhoeae* and six strains of non-pathogenic *Neisseria meningitidis* were also deposited with ATCC as positive and negative controls, and all deposits were described in the patent

specification by referring to their ATCC accession numbers. The 659 Patent further gave a detailed description of the hybridization procedure involving the deposited subcloned fragments and *Neisseria* strains, and a calculation method demonstrating how an isolated *Neisseria* specimen could be identified using the claimed invention.

Enzo sought to enforce the 659 Patent against Gen-Probe and others. The defendants claimed that the 659 Patent was invalid because the deposit of the chromosomal *N. gonorrhoeae* fragments did not satisfy the 35 U.S.C. §112, ¶1 written description requirement. The District Court granted a motion for summary judgment against Enzo, who appealed the decision to the CAFC, which affirmed the District Court's decision.

The CAFC held that a deposit of the vectors contained in the *E. coli* host with ATCC was not an adequate substitute for a written description of the claimed invention in the specification of the patent. The court determined that the specification of the 659 Patent provided only a description of the functional properties of the vectors, *i.e.*, their ability to hybridize to the chromosome of *N. gonorrhoeae*, but no distinguishing information about the identity of the claimed sequences, such as their relevant structural or physical characteristics. The CAFC, citing their earlier holding in *Fiers v. Revel*, restated that an adequate written description of genetic material requires a precise definition, such as by structure, formula, chemical name, or physical properties of the claimed invention, and that a description of what the

invention does, rather than what it is, does not suffice.

The CAFC rejected Enzo's arguments that hybridization is a distinctive chemical property of the claimed sequences, stating that hybridization is merely a functional criterion, not a chemical property that describes a product. The CAFC further stated that Enzo did not identify the regions of non-homology between the claimed sequences of *N. gonorrhoeae* and *N. meningitidis*, nor did they assert that the claimed function (hybridization) was known to correlate to a specific structure or other identifying characteristic that was disclosed in the 659 Patent or was otherwise well known. Thus, the claimed sequences were not distinguishable from other molecules possessing the same activity.

Enzo also unsuccessfully argued that the deposits with ATCC were probative of their possession of the invention, and as such, compliant with the 35 U.S.C. §112, ¶1 written description requirement. The CAFC rejected this argument, distinguishing *possession* from *written description*.

The Court affirmed that possession is not a substitute for compliance with the written description requirement; specifically, possession of three nucleotide sequences does not provide distinguishing information about those sequences for the purpose of satisfying §112 ¶1. The Court acknowledged that Enzo provided certain vague details about the nucleotide sequences, *i.e.*, how they were obtained and their approximate lengths, but this did not rise to the level of a meaningful description of these sequences. The Court then stated that to require the public to

go to a depository and perform experiments to identify an invention is not consistent with the statutory requirement to describe one's invention in the specification.

## What does this mean?

*Enzo* presents several issues for biotech companies to consider if they are seeking to obtain patent protection on their inventions:

- **How much information is necessary to meet the written description requirement?**  
If a polynucleotide or polypeptide composition is part of the claimed subject matter, specific sequence information should be incorporated into the application wherever possible. Additionally, if the claimed invention is best described by function, other identifying characteristics should also be included in the written description. It is critical that the function be related to one or more physical properties to provide a specific identification of the subject matter, such that it can be distinguished from other materials that perform similar functions. Physical properties include, for example, molecular weight, regions of homology/non-homology or interaction with specific sites on a target molecule, isoelectric point, structure, binding affinity or specificity, and other physical properties of the claimed subject matter.
- **Should I even bother making a deposit?**  
This case may not be the final word. *Enzo* is legal precedent for the time being, but Enzo

Biochem has already said they will appeal the CAFC decision to the full court (this case was decided by a three-judge panel), and the case could possibly eventually end up before the Supreme Court. That said, we would recommend continuing depositing material with ATCC where necessary, until this legal situation clears. If you can adequately describe the claimed invention as noted above, however, a deposit of biological material would not appear to be necessary or even advantageous,

and indeed may well be avoided, *e.g.*, for reasons of confidentiality or trade secret maintenance, since once deposited, the biological material is very publicly available. Your Mintz Levin attorney can help advise you for your particular situation.

- **What about my pending patent applications – how does this decision affect them?**

It's hard to say right now. As noted above, *Enzo* is legal precedent for the time being. The court's decision, however, does

appear to be as applicable to pending patent applications as to issued patents, like the patent at issue in *Enzo*. As such, a review of your pending application(s) may be prudent, to ensure the maximum viability and value of your patent portfolio. We would be happy to review specific questions you may have about this case.

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