The Federal Circuit Strikes Again in Enzo-Biochem

THE LATEST ON THE WRITTEN DESCRIPTION REQUIREMENT FOR VALID BIOTECH PATENTS

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On April 2, 2002, the Federal Circuit issued a major decision on the written description requirement (35 U.S.C. § 112, ¶ 1) for biotech patents (see, Enzo-Biochem v. Gen-Probe, __ F.3d. __, 2002 WL 487156 (Fed. Cir. 2002.) In this decision, the Federal Circuit commented upon the PTO's new Guidelines for Examination of Patent Applications Under 35 U.S.C. 112, ¶ 1, 66 Fed. Reg. 1,099 (Jan. 5, 2001) ("Guidelines".)

In a "nutshell," the facts of the case are as follows. Enzo-Biochem developed three nucleic acid probes that selectively hybridized to DNA in N. gonorrhoeae. The probes were deposited for public availability with the American Type Culture Collection. In seeking patent protection for the probes, the patent specification described the probes by their property of binding to N. gonorrhoeae in a preferential ratio of "greater than about five" with respect to N. meningitidis. The specification also included "vague details" regarding how the probes were obtained and an approximate length of the probes. The nucleotide sequence of the hybridization site on the genomic DNA of N. gonorrhoeae was not described.

The district court declared the patent invalid for failure to satisfy the written description requirement. The Federal Circuit affirmed with a published memorandum decision. This decision provides the following practice pointers:

PRACTICE POINTER NO. 1

The Court reiterated its general proposition of law from University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997), that an "adequate written description of genetic material requires a precise definition, such as by structure, formula, chemical name, or physical properties, ... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim ... A description of what the genetic material does, rather than of what it is, does not suffice" (Note, see Practice Pointer 3, infra.)

PRACTICE POINTER NO. 2

Specifying a selective binding affinity (i.e., a function) does not provide an adequate written description where it is the only characteristic describing the claimed nucleotide sequence. The Court rejected "Enzo's characterization of hybridization as a distinctive 'chemical property' of the claimed sequences." The Court opined that "[d]escribing a complicated molecule by means of a broad generic term (a nucleotide sequence) plus its function fails to distinguish it from molecules that can perform the same function" (Note, see Practice Pointer 3, infra.)

PRACTICE POINTER NO. 3

The Court left open the possibility that a functional description could serve as an adequate description under circumstances where "the claimed function is known to correlate to a specific structure or other identifying characteristic that is disclose or otherwise well known."

The Court made the following statemer which infers that a description based o ability to hybridize would be an adequat where there is sequence information on th hybridization site:

> "Thus, in the absence of sequence information for its hybridization site, a nucleic acid described only by its ability to hybridize with another DNA fails to meet the requirements of §112, ¶ 1."

The Court discussed with appare approval the illustration in the Guidelin of a monoclonal antibody binding to ant gen X as being an adequate writte description considering "the well defin structural characteristics ... of antibo the functional characteristics of antibo binding, and ... the technology is w developed and mature."

PRACTICE POINTER NO. 4

The Court rejected that making deposit provides an adequate writt description. In so holding, the Court w unpersuaded by the argument that t genetic material in the deposit could sequenced. The Court explained th deposits are not part of the specificati and their purpose is to satisfy enableme requirements. The specification itself m provide a description "sufficient to aid the resolution of issues of infringemer and "adequate ... for proper examinatior the application."

PRACTICE POINTER NO. 5

The Court clarified that the writ description requirement is not necessa satisfied where the claimed subject mat is described in the patent specification *ipsis verbis* (i.e., the claim language copied over verbatim, or near verbatim, i the specification.) This is known as "Original Claim Doctrine." The Cc stated that if a purported description d not meet the requirements of the stat the fact that it appears as an original cl does not save it. The Original Cl Doctrine is useful where the issue showing possession of the claimed sub matter; e.g., when seeking priority fron earlier filed application, adding new cla during prosecution or meeting a count i interference. IPT