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## INTELLECTUAL PROPERTY LAW

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### Describing Biotech Inventions

Biotech inventors should err on the side of disclosing too much information

Unlike supermarket tabloids serving up the latest in the Brangelina saga, adequate patent disclosures of biotechnology inventions benefit the public.

Biotechnology broadly refers to any process involving the modification or manipulation of living organisms. The 1980 landmark Supreme Court decision, *Diamond v. Chakrabarty*, which involved a patent to genetically engineered bacteria, paved the way for patenting of biotech inventions. In general, raw products of nature are not patentable. DNA products which have been isolated, purified, or modified can be patentable. Likewise, so are other biotechnology inventions, such as antibodies, gene therapy, cell and tissue culture, methods involving stem cells, and cloning.

To obtain a patent, an applicant must adequately describe the invention to the public, i.e., meet the written description requirement. The basis for the written description requirement can

be found in the first paragraph of § 112 of the Patent Statute, which states that each patent “specification shall contain a written description of the invention, and of the manner and process of making and using it, as to enable a person skilled in the art to which it pertains...to make and use the same.”

For many years, courts scrambled the written description and enablement requirements of § 112. In 1991, the Federal Circuit, in *Vas-Cath Inc. v. Mahurkar*, established that § 112 “requires a ‘written description of the invention’ which is separate and distinct from the enablement requirement.” Thus, the description in a patent may be sufficient to enable an invention as defined by a claim, but insufficient to comply with the separate written description requirement.

The purpose of this separate written description requirement is to ensure that an inventor cannot claim that which they did not invent. This requirement is often raised in the context of claims that are added after filing of the original application, or in determining priority to earlier filed applications. However, this requirement also applies to original claims. Thus, an original claim may be invalidated on the basis of inadequate or insufficient written description, especially if it is broader than the rest of the disclosure.

To satisfy the written description requirement, an original disclosure must show that the inventor was in possession of the claimed subject matter at the time of filing. It is not enough that the original application merely ren-

der the claims obvious. Although word for word disclosure is not required, the application must reasonably convey to one skilled in the art that the inventor has possession of the invention.

The issue of written description compliance is a question of fact, and must be determined on a case by case basis. However, a few standards exist. Support for every limitation of the claims must be found in the original disclosure. The amount of disclosure required depends on the breadth and specificity of the claims.

The written description requirement serves the quid pro quo purpose of the patent system. That is, the inventor is required to adequately describe his invention to the public to be entitled to any exclusive right to it. An inventor cannot claim anything broader than his contribution to the public. Through this bargain, the patent system encourages innovation, while reducing secrecy, thereby letting later inventors stand on the shoulders of those who came before them.

In 1991, the Federal Circuit first addressed the question of adequate written description for biotechnology inventions. In *Amgen v. Chugai*, the court, treading uncharted biotechnology waters, chose to look to cases involving chemical compounds for guidance. The court reasoned that a “gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials.” Written description

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was found to be inadequate for a claim to DNA when the sequence of DNA was not itself disclosed, but merely a name for the DNA and a general method of isolating it.

The Federal Circuit applied its decision in *Amgen* in the interference context in *Fiers v. Revel* (1993). The court held that a claim to DNA is not adequately described by providing a description of what the DNA encodes, along with a potential method for isolating it. What is required is "a precise definition, such as by structure, formula, chemical name, or physical properties."

The approach of applying chemical precedent to biotech inventions has been criticized on the basis that the two arts are nonanalogous. Biological molecules, in contrast to chemical molecules, are polymers made up of a finite set of building blocks — four nucleotides each for DNA and RNA; 20 amino acids for proteins. Additionally, while the function of chemical molecules are highly dependent on their three-dimensional structure, biological molecules, especially DNA, which is always in the form of a double-helix, are less dependent on three-dimensional structure. Finally, unlike in chemistry, where the discovery of one compound with a specific function provides no clue as to the existence of other similarly functional molecules, the discovery of a biological molecule in one species usually means that there are corresponding similar molecules with similar functions in other species.

The patent at issue in *Regents of the University of California v. Eli Lilly* (1997) disclosed the sequence of a DNA for rat insulin, but broadly claimed any DNA encoding mammalian insulin. The Federal Circuit held that, while the patent provided adequate written description of rat insulin DNA, it did not do so for all mammalian insulin DNAs. The court reasoned that description of DNA "requires the kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the" DNA.

Critics of the *Lilly* decision contend that it sets an almost impossibly high standard. Even one Federal Circuit judge has expressed his dismay at the stringent test set by this decision. In his concurrence in *Moba v. Diamond Automation* (2003), Judge Randall Rader discussed the shortcomings of the written descrip-

tion rule established in *Lilly* as applied to biotech inventions, noting that the "precise definition" standard set in *Lilly* is unduly burdensome in biotech inventions. Under this standard, a definition for a new protein would require "tedious disclosure of thousands of potential permutations of the amino acid sequence that all fall within a proper description of the protein's functions, properties, and DNA source." Rader analogized this to "requiring disclosure for a new software invention, of the entire source code, symbol by symbol, including all source code permutations that would not alter the function of the software," a requirement expressly rejected for by the Federal Circuit for software inventions.

While a description of one species of mammalian DNA does not adequately describe all mammalian DNA, this does not necessarily mean that any biotech patent claiming broad mammalian genera fails to pass written description muster. In *Amgen v. Hoechst Marion Roussel* (2003), the patent at issue claimed mammalian cells used to produce a non-naturally occurring protein product, but only disclosed methods of producing the protein in hamster and monkey cells. The Federal Circuit held that the specification adequately described the full breadth of the claims, even though methods involving only two mammalian species were disclosed.

The seemingly hard and fast rule of requiring disclosure of full nucleotide sequences set out in *Lilly* may be relaxing, which is good news for biotech inventors. The patent office issued written description guidelines in 2001, along with training materials. Under the guidelines, a DNA molecule can be adequately described by "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In *Enzo Biochem v. Gen-Probe* (2002), the patent at issue did not disclose a full nucleotide sequence of the claimed invention. Instead, the claimed DNA was described by description of its function and reference to deposits of the DNA at a publicly accessible depository. The Federal Circuit held that the written description requirement of a claimed DNA may be met in such a case.

The Federal Circuit has rejected the notion that a complete recitation of nucleotide sequence was required for sequences which are already known in the art. In *Capon v. Eschhar* (2005), the court found adequate written description for chimeric genes made up of sequences which had previously been disclosed, without disclosure of the actual sequences in the patent itself.

Further, the description of a full protein sequence may provide adequate written description for all DNA sequences that can encode the protein. The Federal Circuit stated in *re Wallach* (2004), that there is "no reason to require a patent applicant to list every possible permutation of the nucleic acid sequences that can encode a particular protein for which the amino acid sequence is disclosed." However, the court held that disclosure of only a partial sequence of a protein, combined with some of its physical properties and biochemical activity, were insufficient to support claims to DNA encoding the protein.

Written description standards are easier to meet for inventions involving antibodies than for DNA inventions. In *Noelle v. Lederman* (2004), the Federal Circuit decided that if an application describes a fully characterized antigen, the application may properly "claim an antibody by its binding affinity to that described antigen." An antigen can be fully characterized "either by its structure, formula, chemical name, or physical property, or by depositing the protein in a public depository." Thus, unlike DNA, an antibody may be claimed without ever providing a physical description of the antibody, so long as there is a disclosure of the antigen to which it binds.

Although it's well settled that a description of function alone is not generally sufficient to satisfy the written description requirement for biotech inventions (except in the case of antibodies), how much other information needs to be included for each particular biotech invention must be evaluated on a case-by-case basis. Biotech inventors will do well to err on the side of disclosing more than they think they need. Otherwise, their patent may turn out to be just a piece of paper with no more value than a copy of *The Enquirer*. ■