

# **Haste Without Waste**

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Inventors are always encouraged to file patent applications as early as possible to secure a filing date. The potential downside to an early filing is a finding by the patent office or a court that the claims are not fully supported by the data in the application. This article looks at two important recent international decisions and concludes with tips for ensuring broad patent protection.

## **EPO Opposition Proceeding**

The European Patent Office Board [Re ICOS Corporation, OJ EPO 05/2002] considered allowed claims that included an isolated receptor DNA sequence and its predicted amino acid sequence. The applicant stated that the invention was a transmembrane receptor having a nonobvious function in immunological processes. The Opponents argued that the application merely provided another example of a known type of transmembrane receptor and provided no evidence that the receptor had a unique function in immunological processes. The Board revoked all the allowed claims due to lack of inventive step and lack of credible function for the sequences.

The claimed DNA sequence was isolated using degenerate primers designed from regions of high amino acid similarity between several known receptors. The predicted function of the transmembrane receptor was based on sequence similarity of previously identified transmembrane receptors. No experimental functional characterization data was provided.

The DNA sequence was found obvious in view of prior art that disclosed over 70 DNA sequences for transmembrane receptors, including two sequences that the patentee used to design its primers. Further, the prior art suggested strategies to identify similar receptors. Since the DNA sequence was identified with known procedures and there was no credible evidence for the alleged unique function, the Board found no inventiveness (i.e. it was just another example of a known receptor).

Often, claims for a protein sequence can be supported by a disclosure of the sequence with predictions of its unique function and description of routine methods of verifying the function. For example, by predicting the receptor activity and limiting the candidate ligand compounds to specific groups. However, in this case the claimed protein was held to be insufficiently disclosed. The patent application described a predicted function for the transmembrane receptor, along with several methods to verify the function. The specification did not limit the candidate ligand compounds to any specific group of compounds, so the methods to verify the allegedly unique function of the receptor required undue experimentation (ie. potentially screening millions of candidate compounds).

## **United States Court of Appeals**

DNA sequences can always be modified to circumvent the scope of a patent claim to a particular DNA sequence. Therefore, a patent applicant desires claims that include as many sequence variants as possible. A recent case discussed a patent which claimed a DNA sequence by function alone, that is, without reference to specific DNA sequences (*Enzo Biochem, Inc. v. Gen-Probe Incorporated*, 01-1230, decided April 2, 2002 by the Court of Appeals for the Federal Circuit).

In *Enzo*, the patent claimed antisense DNA probes that selectively hybridize to the genetic material of the gonorrhea bacteria, *N. gonorrhoeae*. The probes were claimed solely by reference to their ability to preferentially detect *N. gonorrhoeae*.

The Court of Appeals concluded that the probes did not satisfy the written description requirement because they were defined only by their function, the ability to preferentially hybridize to *N. gonorrhoeae*. The Court held that an adequate description must allow a person skilled in the art to visualize the subject matter of the claim. Merely describing the function of a DNA sequence is not sufficient.

### **Patent Pointers**

The above decisions illustrate the risks of filing a patent application without complete details of the invention, either because the invention is still at an early stage or because of omission. Patent applications should always be filed expediently with data as complete as possible, in order to establish priority ahead of competitors. Additional data should be protected quickly, for example, by filing additional provisional applications once new data is collected. If the data in the first application is found to be inadequate to support the claims, an early second filing date becomes critical.

A complete description of the sequences should include and emphasize their function. In some patent offices, particularly the EPO, it is difficult to patent a DNA sequence if it is merely an additional or alternate DNA, similar to known types of DNA. The patent application should emphasize the unexpected structural and functional differences of the DNA and its protein compared to the prior art (preferably this emphasis is made by reference to data). If claiming a protein based on predicted function, ensure that the methods for validating the proposed function may be implemented without undue experimentation.

Although it is critical to describe function in the application, DNA and protein claims based on function alone are less likely to be patentable than sequence claims. Therefore, consider protecting sequence variants with claims that incorporate both structural and functional aspects, for example, claims for any DNA that hybridizes to the specific DNA sequence of the invention.