Article: The Federal Circuit Cracks Down on DNA Inventions of Uncertain Utility: The *Fisher* Case

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Research institutions and certain biotechnology companies may breathe a bit easier now. That's because, last month, the Federal Circuit affirmed a decision of the Board of Patent Appeals and Interferences finding patent claims for "expressed sequence tags" unpatentable for lack of utility and lack of enablement.

The case, *In re Fisher,* No. 04-1465, 2005 WL 2139421 (Fed. Cir. Sept. 7, 2005), was closely followed in biotech circles. By affirming the finding of unpatentability, the Federal Circuit has likely ended a rush to patent certain small pieces of DNA sequence that can give researchers a quick and cheap way to discover new genes, get data on gene expression and regulation, and construct genome maps. The Federal Circuit has also laid down important new precedent governing the utility requirement of 35 U.S.C. § 101, a provision often forgotten in other areas of patent law.

The result: Some patent applicants in the biotech field will have to work harder to attain allowable subject matter. Also, biotech companies that are working on identifying expressed sequence tags will have to reap the rewards of this work through something other than patent law, unless they can show the utility of the underlying genes.

Expressed sequence tags, or "ESTs," are small pieces of DNA sequence that are created by sequencing one end of an expressed gene. In simpler terms, a gene (DNA) is first converted, or transcribed, into messenger RNA ("mRNA"). The mRNA contains only the parts of the gene that code for proteins. Scientists then use special enzymes to convert the mRNA into complementary DNA ("cDNA"), which can be taken outside of a cell. Next, scientists figure out the sequence of the "nucleotides" at one end of the cDNA molecule. This piece of DNA sequence is the EST. The EST can be used as a landmark to identify the gene in the future.

In the *Fisher* case, two Monsanto scientists filed a patent application claiming five nucleotide sequences from the cells of a maize plant. The scientists knew the makeup of these ESTs, but did not know the precise structure or function of either the corresponding genes or the proteins encoded for by those genes. The patent application stated that the five claimed ESTs could be used in several ways, including (1) serving as a marker for mapping the maize genome; and (2) measuring the level of mRNA in a tissue sample.

The Federal Circuit found that none of the stated ways in which the ESTs could be used met the utility requirement of 35 U.S.C. § 101. Section 101 states that "[w]hoever invents . . . any new and useful . . . composition of matter . . . may obtain a patent therefor . . ." The Federal Circuit proceeded to review the history of the utility requirement, quoting the Supreme Court's conception of the requirement in *Brenner v. Manson,* 383 U.S. 519 (1966): "Unless and until a process is refined and developed to this point [of 'substantial utility'] -- where specific benefit exists in currently available form -- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." *Id.* at 534-35. The Federal Circuit then summarized the inquiry as follows: "[T]o satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public . . . .[A]n asserted use must also show that claimed invention can be used to provide a well-defined and particular benefit to the public." *Fisher,* 2005 WL 2139421 at *5.

In the Federal Circuit's view, the problem with the claimed ESTs is that, while each EST uniquely corresponds to a single gene, "the underlying genes have no known functions." *Fisher,* 2005 WL 2139421 at *7. In other words, the ESTs fail to meet the utility requirement because it is not clear whether the underlying genes have any utility. It would be one thing if we knew that the underlying gene could be used to cure Alzheimer's. Here, there is only a possibility that the underlying gene might be found useful in the future.

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Was the Federal Circuit right? In the appeal, the Monsanto scientists compared ESTs to other patentable research tools, such as a microscope. They argued that microscopes and other patentable research tools do not necessarily yield specific and presently available benefits, so ESTs should not be held to such a standard. In his dissent, Judge Rader chastised the panel majority for denying "the very nature of scientific advance," which "always advances in small incremental steps ....Often scientists embark on research with no assurance of success and knowing that even success will demand 'significant additional research.'" *Fisher,* 2005 WL 2139421 at *14.

In truth, ESTs must have some utility in the colloquial sense. Otherwise Monsanto and other biotech companies would not be giving this case so much attention. But the utility of ESTs seems to be in making it easier for scientists to determine in the future whether the specific underlying genes are useful. This appears to be where the Federal Circuit draws the line. A microscope has the general utility of "optically magnifying an object to immediately reveal its structure." *Fisher,* 2005 WL 2139421 at *7. It is not tied to a specific object and its benefit is immediate -- you get to see an object up close. ESTs, in contrast, are useful for marking only a particular gene or measuring the level of only a particular mRNA, and this is beneficial only if the specific gene or mRNA turns out to be beneficial. As a group, a databank of ESTs has great utility; individually, their utility may be insubstantial.

But even a single EST has a use -- to serve as a marker for a gene in future scientific study. Why should the Federal Circuit be judging whether that use provides a significant benefit from a scientific standpoint? That is a key part of the dissent of Judge Rader, who rails against the panel majority for "acknowledg[ing] that the ESTs perform a function, that they have a utility," while at the same time "proceed[ing] quickly to a value judgment that the utility would not produce enough valuable information." *Fisher,* 2005 WL 2139421 at *14.

Judge Rader does have doubts about whether ESTs ultimately should be patentable, but he advocates using the obviousness requirement of 35 U.S.C. § 103 as "[t]he proper tool for assessing sufficient contribution to the useful arts." *Id.* at *16. The problem says Judge Rader, is that the Federal Circuit took the teeth out of the obviousness requirement for genomic inventions in *In re Deuel,* 15 F.3d 1552 (Fed. Cir. 1995) (holding that "the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs"). In the end, however, Judge Rader does not explain why, if the Federal Circuit should be avoiding value judgments about the usefulness of scientific achievements under the utility requirement, it might be acceptable for the court to make similar judgments about whether the achievement advanced the "useful arts" sufficiently to survive the obviousness requirement.

At the end of the day, for those who believe that allowing EST patents would discourage research and delay scientific discovery, the *Fisher* decision was the right one. For those who favor strong patent protection for research tools, even if the future real-world benefits are highly speculative, the *Fisher* case is a step backward.

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