Comment 4 George Corey

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From: George Corey [SMTP:gcorey@mediaone.net]
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Subject: Somments on REVISED INTERIM GUIDELINES FOR EXAMINATION OF PATENT APPLICATIONS

SUBMISSION TO UNITED STATES PATENT AND TRADEMARK OFFICE
MARCH 22, 2000

SUBMISSION IN RESPONSE TO REVISED INTERIM GUIDELINES
FOR EXAMINATION OF PATENT APPLICATIONS UNDER THE 35 U.S.C. Sec, 112
ISSUED IN THE FEDERAL REGISTER 64 FR 71,427 ON DECEMBER 21, l999

SUBMITTING PARTY: This submission is made by George D. Corey, 65 Harding Street, Newton, MA 02465.

I respectfully submit that the United States Patent and Trademark Office (the "PTO") has erroneously interpreted the principles of the US Patent Laws by issuing by issuing the Revised Interim Guidelines that evidence an intention to allow theoretical patents on genes (cDNA) and expressed sequence tags ("EST") and their related uses (known altogether as "gene patents" herein) wherein the putative function and use is based largely on homology to known DNA sequences. Issuing such patents undermines the patent system based by allowing overly broad patent coverage in areas never contemplated thus impairing research and diminishing the need for any true act of inventiveness.

Theoretical gene patents should not be allowed where putative function and/or use is based primarily on DNA homology:

Theoretical gene patents based on DNA homology have mistakenly been considered to be required by case law and this proposition is now memorialized in these proposed guidelines. However, the courts do not require the Patent Office to engage in the issuance of such patents.

This notion was confirmed when Mr. Doll of the USPTO at a recent gene patenting conference in Washington, DC remarked that his office would reconsider the proposed guidelines regarding theoretical gene patents, if examples of homologous DNA could be found where the DNA (and/or resulting its gene product) behaved differently than predicted. Here are some examples of

homologous DNA (and related gene products or events) that do behave in a predicted manner (e.g. different ligands, cellular effects, etc.).

Example 1: Epidermal Growth Factor Receptor (EGF-R) and the neu oncogene. Bob Weinberg, Whitehead Institute.

These proteins are rather similar, but their ligands are quite different and their functions are also different. Even though EGF and the EGF-R were well known, it took many years after neu was identified before the ligand was found. The neu oncogene and the ligands (heregulins) are relevant to breast cancer.

Example 2: G-Protein Coupled Receptors (GPCRs) for dopamine and serotonin. RJ Lefkowitz, Duke.

The receptors are very similar, but serve as receptors for very different neurotransmitters with different functions and expression patterns.

Example 3: Nuclear hormone receptors. Keith Yamamoto, UCSF.

A large family of genes, that interact with 1) an extremely diverse set of hormones, or 2) no hormones at all, and can turn on gene expression, turn it off, or do either depending on the circumstances. It is very difficult to predict function, even of very closely related genes.

More recently, the CCR5 patent issued to Human Genome Sciences (HGS) raises a related problem attendant with theoretical gene patents, namely, the failure to precisely understand the effects on cellular functions in a meaningful way. Futher research done by others (not HGS) demonstrated that the gene product (or a significant variant thereof) was shown to be a receptor for the AIDS virus. However, Human Genome Sciences intends to collect a royalty on any such use despite the fact that its patent did not teach that the protein (or variant thereof) could be a target for AIDs intervention and treatment. In effect, this is like patenting a hydroplane with a propeller and then claiming that the patent covers airplanes because both have propellers, wings for lift and cut through air at some level. Such theoretical patents are overbroadly and in effect do not accurately cover what was actually invented, if anything at all and such patents provide a continuing basis for extensive litigation, thereby delaying or impairing commercialization of such research (e.g. new therapies, diagnostics).

Allowing such theoretical gene patents based on computer determined homology also demonstrates that no creative act of invention occurred (especially as the three (3) examples above illustrate).

Moreover, it is important to note that current patent law provides inventors with substantial protection against related inventions under "the doctrine of equivalents."

For all of these reasons above, the proposed guidelines regarding approving theoretical gene patents based largely on computer generated homology should be expunged from the revised guidelines.