Comment 43 National Breast Cancer Coalition/Fran Visco

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To: 'mark.nagumo@uspto.gov'
Subject: Comments on the Revised Utility Examination and Written Description Guidelines

March 22, 2000

Mark Nagumo
Commissioner of Patents and Trademarks
U.S. Patent and Trademark Office
Box 8
Washington, D.C. 20231

Dear Commissioner Nagumo

I am writing to you on behalf of the National Breast Cancer Coalition (NBCC), and the 2.6 million women living with breast cancer. NBCC, a grassroots advocacy organization made up of over 500 organizations and tens of thousands of individuals, has been working since l99l to eradicate breast cancer through increased funding and new strategies for breast cancer research, access to quality health care for all women, and expanded influence of breast cancer activists at every table where decisions regarding breast cancer are made.

The following comments are in response to the Patent and Trademark Office's (PTO) request for public comment on its proposed Revised Written Description and Utility Examination Guidelines. While NBCC appreciates the PTO's efforts to issue stricter guidelines regarding the patentability of genes and gene fragments, we remain concerned about the impact of the PTO policies on medical research.

NBCC strongly believes that gene patenting should not impede biomedical research progress. To realize the full potential of genetic research, scientists should have free access to the raw fundamental data on the human genome. Such unencumbered access would benefit the public by providing the greatest opportunity for scientific advancements against diseases. Patenting naturally occurring genes and disease-causing mutations stifles the research process.

Awarding patents for genes at any stage of research deprives others of the incentive and the ability to continue exploratory research and development.

However, patenting of partial and uncharacterized DNA sequences is especially disturbing since it unfairly gives a monopoly to companies who have only listed potential uses of these fragments without understanding their true biological functions.
Cutting off further research at this early stage gives those who patent pieces to the human genome fastest a great deal of control over any effort to expand scientific knowledge about them. Granting exclusive licenses allows patent owners to control the flow and direction of research - by limiting how genetic tests are done, which mutations will be tested for, and the number of tests that can be performed. Also, when single entities have sole possession of gene tests, they often raise the cost of these tests to astronomical levels, making the tests too expensive for patients or for wide scale research. While we believe that entities should be financially rewarded for the drugs, biologics, and devices that they have developed, we do not believe that they should profit from patents on raw genetic material in this way.

Not only is the practice of gene patenting against the public interest and harmful to research, it also defies traditional patent principles. United States patent law has dictated that for every patent that is issued, current utility must be shown. However, since scientists have discovered a way to identify short scraps of DNA, known as Expressed Sequence Tags (ESTs), patents have been awarded for general claims for these ESTs -- in the hope that they will be used to find genes on a chromosome -- even when their current utility is unknown and their biological function is undefined. Patent policies should not allow this to happen.

NBCC acknowledges that the PTO is attempting to raise the bar for patent applications with respect to written descriptions and what constitutes acceptable utility for patent purposes. The PTO's proposed three-pronged test for utility, which requires a claimed invention to possess a specific, substantial, and credible utility could help discriminate between genes and gene fragments that currently confer specific benefit and those that are merely potentially useful as objects of further research. Application of this test could help ensure that scientists would have to establish more substantial, real-world utility, and could have a significant impact on the number of patents granted. All patent applications should meet these standards for utility, even in situations where an invention is deemed to possess a "well-established" utility. The PTO should revise the guidelines by requiring complete disclosure supporting allegations or conclusions of "well established" utility by either the applicant or the Patent Examiner.

Similar to our concerns regarding utility, NBCC believes that the proposed Revised Written Description Guidelines should be strengthened. Claims of broad scope for certain gene and partial gene sequences should not be granted patents. By allowing "comprising claims" for partial gene sequences

lacking any known biological function to satisfy the written description requirement, the PTO guidelines could potentially enable entities seeking patents for these partial sequences to assert ownership of any later discovered full length gene containing the claimed subsequence. Such interpretation would discourage research and development. Ambiguities that allow this to occur should be clarified.

We appreciate the opportunity to comment on the Revised Written Description and Utility Examination Guidelines, and look forward to working with the Patent and Trademark Office to improve policies that impact research and public health.

Sincerely,

Fran Visco
President
National Breast Cancer Coalition