UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ASSOCIATION FOR MOLECULAR PATHOLOGY; AMERICAN COLLEGE OF MEDICAL GENETICS; AMERICAN SOCIETY FOR CLINICAL PATHOLOGY; COLLEGE OF AMERICAN PATHOLOGISTS; HAIG KAZAZIAN, MD; ARUPA GANGULY, PhD; WENDY CHUNG, MD, PhD; HARRY OSTRER, MD; DAVID LEDBETTER, PhD; STEPHEN WARREN, PhD; ELLEN MATLOFF, M.S.; ELSA REICH, M.S.; BREAST CANCER ACTION; BOSTON WOMEN'S HEALTH BOOK COLLECTIVE; LISBETH CERIANI; RUNI LIMARY; GENAE GIRARD; PATRICE FORTUNE; VICKY THOMASON; KATHLEEN RAKER,

Plaintiffs,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE; MYRIAD GENETICS; LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG, in their official capacity as Directors of the University of Utah Research Foundation,

Defendants.

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09 Civ. 4515 (RWS)

ECF Case

DECLARATION OF MILDRED CHO, Ph.D.

I, MILDRED CHO, PhD, certify under penalty of perjury that the following is true and correct:

1. I am currently the Associate Director of the Stanford Center for Biomedical Ethics and Associate Professor in the Stanford University Department of Pediatrics, Division of Medical Genetics. I am also the Director of the Center for Integration of Research on Ethics and Genetics, and Principal Investigator of the grant that supports this National Institutes of Health Center for Excellence in Ethical, Legal, and Social Implications (ELSI) Research, which was established to investigate the ELSI of genetic research. I teach courses on the ethics of biomedical research and conduct research on ethical issues in the conduct and application of biomedical research, especially those arising in the field of genetics.

2. I submit this certification in support of Plaintiffs' motion for summary judgment. Based on my research and expertise, in the case of clinical genetic tests, patents on such tests inhibit scientific research, discourage application of research to clinical practice, and are not required to spur innovation. Thus, patents on genetic tests are inhibitory to access to clinical diagnosis and potentially harm patients.

3. I have a BS degree from the Massachusetts Institute of Technology in Life Sciences, a PhD from Stanford University in Pharmacology, and post-doctoral training in health policy from the University of California, San Francisco and from the Center for Health Care Evaluation of the Palo Alto Veterans Affairs Medical Center. Prior to my appointment at Stanford, I was Assistant Professor of Bioethics at the University of Pennsylvania Center for Bioethics.

4. I am a member of several professional organizations, including the American Society of Human Genetics, the American College of Medical Genetics, and the American Society for Bioethics and Humanities.

5. I am, and have served as, an advisor to research and development programs in the United States and other countries regarding the conduct and commercialization of biomedical and

genetic research. These institutions include the National Human Genome Research Institute, the United Kingdom Biobank, the Wellcome Trust, Genome Canada, the World Health Organization, and the Organization for Economic Cooperation and Development.

6. I have conducted empirical research on the effects of commercialization of academic research. A complete list of my publications is contained in my curriculum vitae, attached as an Exhibit.

7. In 1998 and 1999, I conducted preliminary studies to examine the effects of gene patents on laboratories that conduct clinical genetic tests and to examine the nature of the patents themselves and how and whether they were licensed.

8. In 2000, I received a grant from the National Human Genome Research Institute of the U.S. National Institutes of Health (Grant # 1 R01 HG02034) to conduct a series of studies on the effects of U.S. gene patents and licensing practices on genetic research and clinical practice.

Effects of gene patents

9. As part of our NHGRI-funded grant, we performed a systematic telephone survey between July and September 2001 of all laboratory directors in the United States who were likely to be conducting genetic tests. These directors included members of the Association for Molecular Pathology (an organization of professionals who conduct genetic testing in the United States, and a plaintiff in this case), and directors of U.S. laboratories who were listed on the GeneTests.org website (an online clearinghouse of laboratories worldwide that conduct clinical genetic tests).

10. We found that over half of the lab directors who responded to our survey (53%) reported deciding not to develop a new clinical genetic test because of a gene patent or license. Two-thirds (67%) of respondents believed that gene patents resulted in a decreased ability to do research, whereas only 3.4% of respondents believed that gene patents increased the ability to do research. Another study of members of the American Society of Human Genetics reported

similar results, finding that 46% of respondents felt that patents have delayed or limited their research (Rabino, I., 2002, How human geneticists in US view commercialization of the Human Genome Project. *Nature Genetics* 29:15-16).

11. We also found that 25% of respondents reported that they had stopped performing a clinical genetic test because of a gene patent or license (Cho, MK *et al.,* 2003, Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services, *Journal of Molecular Diagnostics* vol. 5, no. 1, pages 3-8.)

12. We contacted all 211 laboratory directors identified in June 2001 and received responses from 132 (63%). Of these, 10 were excluded because they did not perform DNA-based genetic testing. Respondents did not differ in a statistically significant way from nonrespondents in the likelihood of being from a for-profit or not-for-profit institution (P=0.37).

13. The majority of respondents (65%) said that their laboratories had been contacted by a patent or license holder regarding the laboratory's potential infringement of a patent by performance of a genetic test. These notifications were regarding the conduct of several genetic tests, including of BRCA1/BRCA2 genes.

14. We asked the 25% of laboratory directors reporting that they decided to cease offering a clinical test because of a patent or license which tests they ceased to perform. These laboratories reported ceasing to perform 12 clinical tests, including the BRCA1 and BRCA2 tests for hereditary breast and ovarian cancer.

15. To put these 12 tests into context, we found that 461 genetic tests were offered in the GeneTests database as a clinical service, the vast majority of which (394) were for rare disorders and performed by 10 or fewer laboratories (of the 133 laboratories identified in GeneTests who conduct genetic tests). However, all of the 12 tests that laboratories had stopped performing were offered by 11 or more laboratories. This finding suggests that patents affect laboratories that test for and patients who have more common conditions.

16. A total of 9 respondents reported that they had stopped performing tests for BRCA1 and BRCA2 because of patents. More laboratories had stopped performing BRCA1 and BRCA2 tests than any other test, with the exception of Apolipoprotein E (Apo E). Nine respondents reported having stopped performing tests for Apo E.

Role of patents in innovation and commercialization

17. Other studies that we conducted indicate that gene patents are not required to bring discoveries into commercial production or clinical practice, and that gene patents are also not required as incentives to spur the initial discoveries because the majority of patented gene discoveries were supported by the federal government.

18. We conducted a study of patenting and licensing of a specific genetic test for hemochromatosis, a common condition affecting 1 in 200 to 1 in 300 people of Northern European descent, with a carrier frequency of up to 1 in 10.

19. We identified 117 laboratories through GeneTests and the Association for Molecular Pathology tests directory and 11 additional laboratories through snowball sampling for a total comprehensive sample of 128 laboratories conducting hemochromatosis testing in the U.S. in 1999. We received responses from 119 laboratories (93%).

20. Thirty-one laboratories (26%) reported that they had not developed and were not performing the hemochromatosis test, and 5 (4%) had stopped performing the test, with 32 of 36 citing patents as a reason. Thus, as we found for other genetic tests, the existence of a patent had a significant impact on laboratories that could have offered the hemochromatosis test.

21. While awareness of a patent on the hemochromatosis test appeared to inhibit the adoption by clinical laboratories, patents were not necessary for rapid introduction of the test. Patents on the test were filed in mid-1995 through mid-1996, and the first publication of the discovery of the hemochromatosis gene appeared in August, 1996. Laboratories immediately began offering clinical genetic tests for hemochromatosis, with the mean time from publication to adoption (by

laboratories represented in our survey) of 14 months. Indeed, 60% (35 of 58 performing hemochromatosis testing at the time of our survey) reported introducing the clinical test *before* the first patent was issued in January 1998.

22. Another study of gene patents issued in the U.S. on genetic diagnostics showed that two-thirds (67%) were for discoveries funded by the US government (Schissel, A., Merz, JF., Cho, MK., 1999. Survey confirms fears about licensing of genetic tests. *Nature* 402:118.) This is another indication that patents themselves are not necessary for initial discoveries relevant to clinical genetic diagnostics. This preliminary study identified 33 U.S. patents issued in 1991-1997 that broadly covered the diagnosis of human genetic disorders held by U.S. institutions and that were not expired. Of these 33 patents, 22 were funded at least in part by the U.S. government.

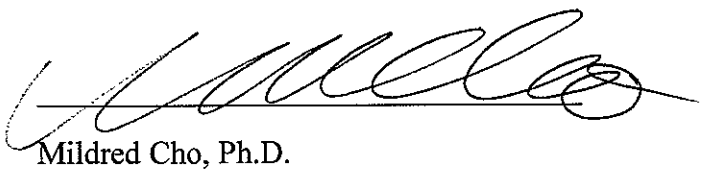
23. Therefore, perhaps unlike other discoveries such as chemical compounds that have pharmaceutical potential, and that require lengthy and expensive further development in order to become commercially available and accessible to patients, in the case of genetic findings relevant to clinical tests, the exclusivity offered by patents is not necessary to incent either the initial discovery or its clinical application.

Conclusions

24. Thus, our results provide evidence that patents on genes used for clinical diagnostics inhibit the conduct of research to further the development of improvements to genetic tests. Our findings also provide evidence that such patents inhibit clinical diagnostic laboratories from providing clinical tests and services.

25. We have also found evidence that, at least for gene discoveries relevant to clinical diagnostics, patents are not necessary to incent either the research on initial discoveries or the development of clinical applications and commercializable products.

I declare, pursuant to 28 U.S.C. §1746, under penalty of perjury under the laws of the United States, that the foregoing is true and correct to the best of my knowledge and belief.



Mildred Cho, Ph.D.

Executed on August 17, 2009