

Mandating Race: How the PTO is Forcing Race into Biotechnology Patents

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How Does Race Enter Biotechnology?

- Unintended Consequences of Federal Mandates
 - ◆ NIH Revitalization Act
 - ◆ FDMA
- Commercial Advantage
 - ◆ Affirmative Patent Exploitation – BiDil
 - ◆ Defensive Patenting
 - ◆ Market Differentiation – Bystolic

Federal Mandates

- NIH Revitalization Act - 1993
 - ◆ Mandate collection of data by race, ethnicity, gender
- Food and Drug Modernization Act – 1997
 - ◆ Encourage submission of data broken down by race, ethnicity and gender.

BiDiI

- Non-Racial Patent Expired 2007
- Racial Patent (for Blacks Only) Extends to 2020
- Supports race-specific:
 - ◆ Trial Design
 - ◆ FDA Approval
 - ◆ Marketing

Defensive Patenting:

“Detection of susceptibility to autoimmune diseases” (U.S. Patent Application #20040126794)

1. A method for determining an individual's risk for type 1 diabetes comprising: detecting the presence of a type 1 diabetes-associated class I HLA-C allele in a nucleic acid sample of the individual, wherein the presence of said allele indicates the individual's risk for type 1 diabetes.
2. The method of claim 1, wherein the individual is of Asian descent.
3. The method of claim 1, wherein the individual is of Filipino descent. [emphasis added]

Market Differentiation

- Bystolic – Making the 18th Beta Blocker Stand Out
- Race-Specific Clinical Trial (for Blacks)
- Race-Specific Information in FDA Label
- Race Specific Patents
 - ◆ Blacks
 - ◆ Mexican

A New Model: Affirmatively Mandating Race

- Presentation to “Customer Partnership” meeting
- Cases on Appeal
- Patents never appealed

PTO Customer Partnership Presentation - 2008

- “Prior art teaches that ethnicity is an *unpredictable* factor in single nucleotide polymorphism (SNP) correlation studies”
- Studies published after the filing of the patent application indicated that “breast cancer drug X” was ineffective for African-Americans.
- Conclusion: Because effectiveness for all races was not established, “a scope of enablement rejection *must* be considered.”

-- Kathleen Bragdon, PTO Quality Assurance Specialist

Cases on Appeal

- US Patent Application No.
- **Rejected** by examiner because one of the relevant mutations was found in Caucasians, while another was found African Americans, hence: it “has not [been] shown that the correlation between the claimed mutations and the risk of both sporadic and hereditary prostate cancers is significant in all populations.”
- **Overtured by BPAI:** Ex Parte Jianfeng Xu, Deborah Meyers, Sigun Zheng, Patrick C. Walsh, William B. Isaacs, Eugene Bleecker, and David Herrington. 2009 WL 819042 (Bd.Pat.App. & Interf.) 2009, 3.

Patents Never Appealed

- #6,716,581: Manganese superoxide dismutase gene polymorphism for predicting cancer susceptibility
- Original First Claim: “A kit for determining whether a subject has, or is at risk of developing, colorectal cancer wherein said kit is used to amplify and/or determine the molecular structure of at least a portion of the MnSOD gene.”

PTO Mandate

■ Patent Examiner's Denial:

- ◆ “Given the **unpredictability** in the art of genetic diagnosis, one cannot extrapolate the findings obtained with a single **ethnic group** to the general population.”

■ Ultimate First Claim in Patent:

- ◆ “A method of determining relative age-related risk of colorectal cancer in a Hispanic subject, comprising . . .”

Results

- Federal Government Mandating the Biologization of Race
- Perverse incentives regarding the use of race/ethnicity in biomedical research
- Geneticizing Disparities
 - ◆ Blame Genes not Injustice

EPO: An Alternative Approach

- EP1509242: TREATMENT OF HEPATITIS C IN THE ASIAN POPULATION WITH SUBCUTANEOUS INTERFERONBETA - Merck Serono S.A.,
- Rejected:

“The present application **does not clearly define ‘Asian race.’** Therefore the claims fail to comply with article 84 EPC to such an extent that no meaningful examination of novelty and inventive step appears possible.” – 4 April 2011.