July 14, 2014

Mail Stop – Comments
Commissioner For Patents
PO Box 1450
Alexandria, VA 22313-1450

To the Commission For Patents:

Please accept my comments regarding the Myriad-Mayo examination guidelines.

I suggest the institution of an Independent Review Committee in the Patent Office.
The body would review applications claiming Myriad or Mayo type subject matter prior to grant, taking into account the ethical implications of the patent should the application be granted.
More details are found in my book "Other Peoples Bodies" on pages 80-81.
A link to my book is found here.
A copy of the book is forwarded to the USPTO under separate cover.

Thank you for your consideration.

Arthur P. Gershman

Respectfully submitted,
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RN 27,035

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The Department of Justice Brief

In a startling development, the U S Department of Justice submitted an amicus brief striking a compromise position between the two sides. The DOJ position is that patent claims directed to genetically engineered molecules, including cDNAs are patentable, while the claims directed to the isolated DNA per se not. This position completely ignores the ethical considerations behind the arguments of those who think that all DNA patents should be prohibited.

The Independent Ethics Committee

In direct response to research abuses in the twentieth century, particularly the experiments of Nazi physicians that became the focus of the post-World War II Nazi Doctors Trial, the Independent Ethics Committee (IEC) was developed.

The IEC, also known as an Institutional Review Board (IRB), or Ethical Review Board (ERB), is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects. In the US the FDA and DHSS (specifically Office for Human Research Protections) regulations have empowered IRBs to approve, require modifications in planned research prior to approval, or disapprove research. An IRB performs critical oversight functions for research conducted on human subjects that are scientific, ethical, and regulatory.

Examining the nuts and bolts of the IRB:

(a)1 The IRB must have at least five members.

(a)2 The members must have enough experience, expertise, and diversity to make an informed decision on whether the research is ethical, informed consent is sufficient, and appropriate safeguards have been put in place.

(a)3 If the IRB works with studies that include vulnerable populations, the IRB should have members who are familiar with these groups. It is common for an IRB to include an advocate for prisoners when considering research that involves them.

(b)1 The IRB should include both men and women, as long as they aren't chosen specifically for their gender.

(b)2 The members of the IRB must not be all of the same profession.

(c) The IRB must include at least one scientist and at least one non-scientist. These terms are not defined in the regulations.

(d) The IRB must include at least one person who is not affiliated with the institution or in the immediate family of a person affiliated with the institution. These are commonly called "Community Members."

(e) IRB members may not vote on their own projects.

(f) The IRB may include consultants in their discussions to meet requirements for expertise or diversity, but only actual IRB members may vote.

In order to vote on a proposal, more than half of the members of the board must be present and there must be a non-scientist present. There are exceptions for expedited review, where only the chair of the committee or a designee reviews research, but these are relatively narrow. This information is from 45 CFR (Code of Federal Regulations) Part 46, 56 - INSTITUTIONAL REVIEW BOARDS". Food and Drug Administration (United States). 28 June 1991. Retrieved May 12, 2009. A similar policy is also codified for the Commerce Department at 15CFR27.

Codifying an IEC mechanism to vet patents on human genes, similar to the IRBs used to vet human experimentation, may be one way out of the dilemma which we find ourselves in today.