Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials

Gregory Dolin
Associate Professor & Co-Director of the Center for Medicine and Law
University of Baltimore, School of Law
gdolin@ubalt.edu | **Bio**

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Over the last twenty years, the legal and scientific academic communities have been embroiled in a debate about patent eligibility of genetic materials. The stakes for both sides couldn't be higher. On one hand are the potential multi-billion dollar profits on the fruits of research (from newly discovered genes) and on the other is the ability of scientists to continue and expand research into the human genome as well as patients' access to affordable diagnostic and therapeutic modalities. This debate is currently pending before the Supreme Court which has under consideration petition for certiorari in Ass'n for Molecular Pathology v. USPTO.

This paper recognizes that both sides have legitimate concerns. Given the unique nature of DNA, patents that broadly cover genetic materials and prevent their use (except by the license of the patentee) create insurmountable roadblocks for future research. However, denying exclusive rights to the fruits of laborious and costly research will remove the necessary incentives for investment in these endeavors, thus delaying scientific and medical discoveries.

To remedy these problems, the paper proposes a non-patent exclusivity system administered by the Food & Drug Administration. Under such a system, the innovators who bring new therapeutic or diagnostic products to market will receive exclusive rights to market their products for a limited time. This will provide sufficient market-based incentives to continue with the research and investment in this area. At the same time, because genetic sequences will no longer be broadly protected by patents, the public will be able to access these basic research tools without fear of infringement litigation. This approach addresses concerns of the both sides to the debate, and leads to a cheaper, more predictable, and easier to administer system of exclusive rights.