# TITLE: Therasense Meets the ACLU

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37 CFR 1.56 requires disclosure of material information to the United States Patent and Trademark Office ("USPTO") when applying for a patent. This duty is imposed on (1) each inventor; (2) each attorney or agent who prepares or prosecutes the application; and (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. Thus, for academic institutions, the individuals in the technology transfer office (or whichever entity handles patent prosecution for the institution) are bound by this duty to disclose, and the failure to disclose material information can result in unenforceability of the entire patent. In *Association of Molecular Pathologists v. USPTO*, several named Plaintiffs from Yale, Emory, UPenn, Columbia, and NYU submitted affidavits expressly stating that patents relating to isolated genes should not be patentable. To the extent that these Plaintiffs are also inventors on isolated-sequence-related patents, their affidavits and pleadings contain information that is material to the patentability of their own isolated-sequence-related inventions. Thus, the failure of these inventors to disclose their affidavits to the USPTO may render their isolated-sequence-related patents unenforceable for inequitable conduct. Furthermore, if the individuals in the technology transfer office for Yale, Emory, UPenn, Columbia, and NYU are aware of the filing of these affidavits, which are material to the patentability of isolated-sequence-related patents, then each of these entities had an obligation to disclose those affidavits in every isolated-sequence-related patent application that was then-pending before the USPTO. The failure by the technology-transfer office to disclose this material information may also render all of these institutions' isolated-sequence-related patents unenforceable for inequitable conduct. This presentation examines the possible extent of unenforceability of isolated-sequence-related patents for Yale, Emory, Columbia, UPenn, and NYU. In doing so, we review two (2) cases in some depth: (a) *Therasense v. Becton, Dickinson & Co.*, Case No. 2008-1511 (Fed. Cir., May 25, 2011); and (b) *Assoc. of Molecular Pathology v. USPTO*, Case No. 2010-1406 (Fed. Cir., July 29, 2011).