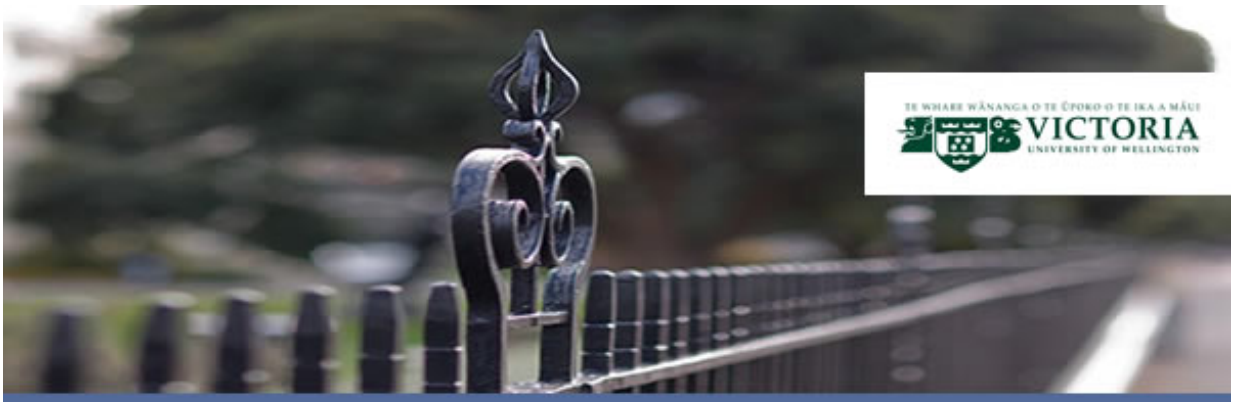

PUBLIC LECTURE

The Patentability of Genetic Diagnostics in US Law and Policy

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A confluence of developments has drawn attention to the issue of patents on diagnostics, particularly to patents involving genetic information used in the diagnosis of familial conditions. In the last two decades, patenting has spread across a range of technological fields and to upstream research. As a result, there are now patent rights covering around 20 percent of the genes said to comprise the human genome, as well as multiple rights to using genetic information to diagnose patients. These patents interpose significant obstacles to patient care, to research, and to the development of promising new techniques, such as multiplex testing, whole genome sequencing, and personalized medicine.

While patents are assumed to spur research and development, it is unclear whether they are needed in the diagnostic realm, where research is largely conducted by academics and clinicians with strong non-commercial motivations, and where the translation of upstream research to downstream application is relatively inexpensive. In the United States, several recent developments have challenged patenting practices in the genetic diagnostic realm: in Association for Molecular Pathology v. US PTO, a trial court invalidated patents on mutations associated with BRCA-type breast cancers as well as patents on the process of using these mutations to diagnose a propensity toward breast cancer. The US Department of Health and Human Services Secretary's Advisory Committee on Genetics, Health, and Society issued a report on gene patenting suggesting a different tack, namely greater transparency in licensing and new exemptions from patent liability for research and diagnosis. Further, the OECD, the US National Institutes of Health, and a consortium of research institutions have issued guidelines, including recommendations for nonexclusive licensing and patent clearing houses and pools.

After examining the problems associated with gene patenting, this paper will discuss the various strategies suggested for improving patient and researcher access. In the process, it will look briefly at two very recent cases, the US Supreme Court's Bilski v. Kappos and the European Court of Justice's Monsanto v.Cefetra.

Tuesday 17 August, 5.30pm
Lecture Theatre 1
Old Government Buildings

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