Patent Policy in Genomics and Human Genetics: A Public Health Perspective

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How is the distention between the natural and technical in patent law constructed by judges and lawyers? Even if we allow patenting and the commercialization of research funded by public money, and put to commercial use whole-sequenced genomes, how can we ensure that society gets back its fair share? How successful are public-private partnerships operating in the spirit of open science, advancing sharing and collaboration? Is the open source model of licensing a viable tool? These are questions that came under a vigorous debate in a workshop on patent policy in genomics and human genetics that I organized at Wolfson College, Oxford on 11 February 2015. The workshop brought together leading academics and key policy makers in the field of genetics and bioethics who discussed the governance of patents in the public interest. The participants of the workshop came up with concrete proposals accommodating both public health needs and the policy urge for competitiveness in local and global markets. To the benefit of policy makers and anyone who shares an interest in the field I outline the workshop's key findings. A detailed report can be found at http://www.fljs.org/content/patent-policy-genomics-and-human-genetics-public-health-perspective-0

The lack of public trust resulting from the commercialization of personal information needs to be addressed

Key Findings

1. Patents may protect technologies, but products of nature fall outside the realm of patent protection. Europe should learn from the current turn in the US jurisprudence on the question of patentability of products of nature, which reflects the concern that the drafting skills of patent attorneys render meaningless the distinction between the natural and the technical in patent law.
2. The European Patent's Office (EPO) Granting Practice is to allow patents on methods and products derived from human embryonic stem cell lines, which were filed after January 2008 if the invention uses the derivation method disclosed by Chung et al. in 2008, which for the first time has allowed the provision of hES cultures (cell lines) without destroying a human embryo in any production step. However, the grounds of this decision should be scrutinized, and the problem of lack of accountability of an administrative agency such as the EPO to the EU legislator needs to be addressed.
3. Public institutions such as the NHS participate in 'hidden' innovation, which escapes measures of quantity and impact applied to the private sector. We need to understand better the amount and quality of this type of innovation and devise policies that accommodate the characteristics of different innovation paths, both public and private.
4. The recent case of Human Papillomavirus testing is just one illustration of the aggressive attempts by private companies to monopolize the market for genetic testing. In the UK, a decision was made on whether to endorse co-testing with the Pap smear test or not, and whether proprietary technology should be used instead of much cheaper tests developed in-house by the NHS. In these cases, policymakers should take into

account that significant first-mover advantage is gained by building a clinical evidence base at an early stage.

5. The Health and Social Care Act 2012 in the UK allows the Health and Social Care Information Centre (HSCIC) to collect and share confidential information from medical records. The subsequent Care Act 2014 means that the public's data can only be shared and analysed when there is a clear healthcare benefit. Beyond well-rehearsed arguments with respect to informed consent, the lack of public trust resulting from the commercialization of personal information needs to be addressed. In this respect, the idea of reciprocal benefit-sharing becomes salient: if a public resource such as the databases held by the National Health System are shared with industry, a reciprocal turn must be secured to enhance the healthcare services that the NHS provides.

6. The 100,000 Genomes Project requires the adoption of a balanced approach to IP to ensure that any commercialization is in the public interest and brings benefits to the NHS. OECD guidelines for the licensing of genetic inventions may serve as a useful model.

7. University technology transfer offices should determine the correct balance between commercial considerations and the translation of technologies to products that serve the needs of the public. On the assumption that social impact should be of primary importance, academic licensing contracts should be structured in a flexible manner to improve access to important technologies.

8. Given the current drive to translate university research into valuable commercial products, it is argued that public institutions lead private companies in the discovery of novel drug targets. The question is whether there is value in filing for patents in early research, or whether to adopt open access policies. Given the declining levels of pharma innovation, serious consideration should be given to the adoption of open science and open source initiatives that redefine the pre-competitive (tools and basic knowledge) and competitive space/proprietary (drug discovery and development) phases, facilitated by access to increased amount of information in the public domain. The management of intellectual property in synthetic biology and other emerging technologies and the ascendancy of open source licensing models present interesting questions for the best way to incentivize future innovation, and should be subject to further research.