# Intellectual asset management in personalized medicine innovation: public policy issues

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## Event

Policy makers generally assume that intellectual property rights (IPRs) play a key role in enabling the translation of new personalized medicine (PM) technologies to patient care (PM is also widely known as precision medicine, see http://paceomics.org/index.php/outputs/policy-briefs/, Brief #10. More recently, scholars have raised sustained concern about the public policy implications of IPRs and related knowledge management practices in biomedical innovation. PACEOMICS presents a comprehensive collection of the academic and policy literature in this domain, annotated by public policy themes. The collection comprises 330 publications authored by researchers and practitioners across more than 60 academic disciplines and 90 non-profit, private, national and international organizations. Downloadable full bibliographic information, annotated guide to the collection, and full methodology at: http://paceomics.org/index.php/outputs/tools-and-resources/

## Significance

IPRs are intended to encourage innovation, yet may act counter to public good under some circumstances. The diminishing market entry of innovative health biotechnology, rising research costs and increasing pressure for cost-effective healthcare all contribute to the need for new and creative approaches to knowledge management[1-3]. Equally, commentators raise concerns about equity and justice in access to novel diagnostics and medicines[1]. Future policy and practice should be informed by the rich discussion that has already taken place. However, the literature in this field occurs across a multitude of academic disciplines and publication types making it difficult to gain perspective on the issues at play.

## Analysis

We carried out a comprehensive search of the policy and academic literature published from 2008 – 2013 following systematic scoping review methods[4]. The search encompassed 16 electronic resources, grey literature searches and additional hand searches of key journals and databases. We imposed inclusion criteria to limit the dataset to target publication types and to peer-reviewed material (for academic documents). Given the large volume of law literature, we limited these publications by journal impact factor. Using thematic content analysis techniques[5], we identified the public policy and socio-ethical issues discussed and categorized each document under a broad theme. The themes include: 1) Alternatives to traditional patents; 2) Enabling access to patented research tools; 3) The impact of IPRs and business models on innovation; 4) IPRs, business models and access to healthcare; 5) Open Science, data-sharing or collaboration; 6) Ownership, informed consent and benefit-sharing; 7) The patentability of biotechnology invention; 8) Patents and 'race'; 9) Religious views on commercialization; 10) The role of IPRs in health biotechnology and precision medicine innovation in developing countries; 11) Social determinants of innovation; and 12) The Role of academic technology transfer offices in facilitating innovation and access. In addition, we annotated the bibliography by publication type and number of citations. For full details and methodology see: http://paceomics.org/index.php/outputs/tools-and-resources/

## Conclusion

PACEOMICS offers an annotated bibliography of literature at the intersection of public policy, intellectual asset management and PM innovation. This resource may be of use to policy-makers, researchers and students seeking to gain in-depth understanding of the issues in this field.

1. International Expert Group on Innovation and Intellectual Property (2008). Toward a new era of intellectual property: from Confrontation to Negotiation. Montreal Canada.
2. Hopkins MM, Hogarth S (2012). Biomarker patents for diagnostics: problem or solution? Nature Biotech, 30 (6). 498 – 500. doi:10.1038/nbt.2257
3. Owens B (2016). Access all areas. Nature, 533. S71 - 72. doi:10.1038/533S71a
4. Arksey H, O'Malley L (2005). Scoping studies: towards a methodological framework. International Journal of Social Research Methodology. 8(1): 19-32.
5. Richie J, Spencer L. (1994). Qualitative data analysis for applied policy research. In Bryman A, Burgess RG, Eds. Analysing qualitative data. London: Routledge: 173-94.