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Precision Medicine and Innovation Law –Some Considerations

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This presentation provides an overview of common aspects of Innovation Law in relation to Precision Medicine, and also bears down on legal issues specific to the area of targeted therapies.

The first part narrates the interrelation between Innovation Law and Precision Medicine. *Precision Medicine* alludes to the customisation of healthcare by way of tailoring appropriate and ideal remedial decisions, treatments and products, based on the genetic constitution of the individual patient or groups of patients. Past policy supporting targeted therapy innovation has proven beneficial, such as, *e.g.*, legislation enacted to aid the development of orphan drugs. Should additional interventions be considered?

The second section relates characteristics of main types of legal protection relevant to Precision Medicine innovation, including mainly patent, trade secret, and data protection law. In continuation these will be explained along with associated leading legal cases, and allusions as to the interplay between these classes will also be made. Data protection will be dealt with, as this asset has become a main driver underlying and increasingly affecting the other legal protection categories.

Patent
Recent legal developments restricting patent eligible subject matter in the US have been foreseen to detrimentally influence Precision Medicine innovation. In the European context, the evolving requirements of 'plausibility' and data submission before the EPO appear to pose challenges for antibody and targeted therapy inventions.

Trade secret
Main cases mentioned include those of the company Myriad, which has been using patient related data for commercial applications after patents on BRCA1 and BRCA2 were struck down, citing trade secret law. This legal protection category is thus also an option for data protection.

Data protection
This subsection will consider the increasing availability of aggregate genetic data and its increasing influence on innovation, the important role of data exclusivity, along with associated privacy protection mechanisms such as the EU GDPR.

The third section emphasises the research or experimental use exemption. As part of patent law in most jurisdictions, an instrument has been introduced and placed in the scales to balance out the real or perceived rigidness of the patent system, to a certain extent allowing assessment in relation to patented subject matter in non-commercial settings.

The fourth section will make a number of conclusions and suggestions for potential policy interventions.

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