

Part III

Analysis De Lege Ferenda: Exclusively Controlled or Readily Accessible?

Part III presents the normative analysis. The key questions are whether a policy intervention enabling access to IPD can be justified on the grounds of promoting drug innovation and, if so, how it should be designed to protect diverse interests at stake and achieve multiple policy objectives in a balanced way. The analysis proceeds as follows. Chapter 6 provides a detailed problem analysis that could inform the ‘intervention logic’ of access measures. Chapter 7 outlines a pertinent theoretical framework for analysing an innovation policy dilemma over access to IPD as a knowledge resource. Chapter 8 explores how theoretical propositions apply in the specific case of clinical trial data. Finally, Chap. 9 evaluates the legislative options for implementing the findings of the legal-theoretical analysis.