



Key Questions on Patent  
Disclosure Requirements  
for Genetic Resources and  
Traditional Knowledge

Second edition



# Table of contents

Foreword	4		
Preface	5		
List of boxes and figures	6		
List of acronyms	7		
1. Introduction	8	10. Geographical scope	33
The aims of this study	8	What is the geographical scope of disclosure?	33
How to use this study	9	11. Exclusions	35
2. Background and concept	10	What exclusions from the material scope of application of a new PDR might be envisaged?	35
What are patent disclosure requirements related to GRs and TK?	10	12. Triggers	36
How do new PDRs related to GRs and TK differ from conventional disclosure requirements under established patent law principles and procedures?	11	What relationship or link between the subject matter of disclosure and the claimed invention will trigger the application of a new PDR?	36
What is the relationship between new PDRs and ABS obligations?	13	13. Remedies and sanctions	39
What are the main critiques and opposing views?	13	What kinds of remedies and sanctions are available to address issues of non-compliance with any new PDRs?	39
3. Objectives	14	14. Evidence	43
Why have several countries introduced new PDRs related to GRs and TK?	14	What evidence might be submitted in the context of new PDR-related compliance mechanisms and procedures?	43
4. Complementary and competing interests and objectives	17	15. Standing	44
What interests and objectives may need to be balanced when shaping an appropriate disclosure obligation?	17	Who might have a right to take legal action for non-compliance with a new PDR?	44
5. Legal nature	20	16. Capacity	46
What is the difference between voluntary and compulsory PDRs?	20	What legal, institutional and policy capacities might be needed to implement a new PDR?	46
6. Formal and substantive requirements	23	17. Relationship with other instruments	49
What role might the patent office play in checking the fulfillment of new formal or substantive PDRs?	23	Under the Nagoya Protocol, is there an obligation to provide for PDRs in order to monitor users' compliance with domestic ABS requirements?	49
7. Placement	24	What are the main implications of establishing the patent/IP office as a designated checkpoint under the Nagoya Protocol?	49
Where should new disclosure requirements be introduced?	24	What is the possible relationship between a new PDR and ABS obligations under the FAO ITPGREFA?	49
Is it possible to introduce new disclosure requirements in legislation other than patent and/or IP law?	24	18. Other measures	52
8. Subject matter	26	Are there alternative and/or complementary measures or mechanisms that can be used to promote PDR-related objectives?	52
What is the subject matter covered by these new PDRs?	26	19. PDRs – a checklist for policymakers	55
9. Content	31	Endnotes	57
What might be the possible content of disclosure?	31	Annex: Disclosure requirements table	61