Sabine Demangue

Intellectual Property Protection for Crop Genetic Resources

A Suitable System for India



Herbert Utz Verlag · München

Rechtswissenschaftliche Forschung und Entwicklung

Herausgegeben von

Prof. Dr. jur. Michael Lehmann, Dipl.-Kfm. Universität München

Band 735

Zugl.: Diss., München, Univ., 2005

Bibliografische Information Der Deutschen Bibliothek: Die Deutsche Bibliothek verzeichnet diese Publikation in der Deutschen Nationalbibliografie; detaillierte bibliografische Daten sind im Internet über http://dnb.ddb.de abrufbar.

Dieses Werk ist urheberrechtlich geschützt.
Die dadurch begründeten Rechte, insbesondere die der Übersetzung, des Nachdrucks, der Entnahme von Abbildungen, der Wiedergabe auf photomechanischem oder ähnlichem Wege und der Speicherung in Datenverarbeitungsanlagen bleiben – auch bei nur auszugsweiser Verwendung – vorbehalten.

Copyright © Herbert Utz Verlag GmbH · 2005

ISBN 3-8316-0517-3

Printed in Germany

Herbert Utz Verlag GmbH, München 089-277791-00 · www.utzverlag.de

CONTENTS IN BRIEF

ACKNOWLEDGEMENTSI
EXECUTIVE SUMMARYIII
LIST OF ABBREVIATIONSXIX
LIST OF TABLESXXIII
LIST OF FIGURESXXIV
CHAPTER 1: INTRODUCTION1
CHAPTER 2: THE INTERNATIONAL LEGAL FRAMEWORK7
CHAPTER 3: THE EUROPEAN SYSTEM OF IP PROTECTION FOR PLANT VARIETIES AND PLANT RELATED BIOTECHNOLOGY INVENTIONS 69
CHAPTER 4: ECONOMIC THEORY OF IPRS AND EMPIRICAL EVIDENCE
CHAPTER 5: PRESENT STATUS OF THE INDIAN SEED SECTOR AND FUTURE CHALLENGES231
CHAPTER 6: THE DEBATE ON POTENTIAL IMPACTS OF PLANT RELATED IPRS ON THE SEED SECTOR IN INDIA285
CHAPTER 7: IP PROTECTION FOR FARMERS' VARIETIES AND RELATED TRADITIONAL KNOWLEDGE335
CHAPTER 8: ANALYSIS OF THE INDIAN PLANT RELATED IPR LEGISLATION401
CHAPTER 9: CONCLUSIONS451
GLOSSARY459
LIST OF CITED EXPERTS AND STAKEHOLDERS CONSULTED ORALLY OR IN WRITING465
REFERENCES467

DETAILED CONTENTS

ACKNOWLEDGEMENTS	I
EXECUTIVE SUMMARY	III
LIST OF ABBREVIATIONS	XIX
LIST OF TABLES	XXIII
LIST OF FIGURES	XXIV
CHAPTER 1: INTRODUCTION	1
CHAPTER 2: THE INTERNATIONAL LEGAL FRAMEWORK	7
A. OBLIGATIONS UNDER THE TRIPS AGREEMENT	7
I. Interpretation of Art. 27(3)(b)	7
1. Plants versus microorganisms	8
a) Plant cells	
b) Plant genes and other DNA molecules	
2. Essentially biological, non-biological and microbiological processes for the production	
plants	
a) Essentially biological processes	
b) Microbiological processes	
c) Non-biological processes	18
3. Plant varieties	18
4. Effective sui generis system	
II. Minimum patent protection for plant related inventions	
1. Patentable subject matter under Art. 27(1)	
2. Offence against ordre public or morality as ground for exclusion from patentability	
a) Necessity to prevent commercial exploitation	
b) Protection of ordre public or morality	28
c) Infringement of national rules on access to biological resources laws as case of	
Art. 27(2)?	
3. Margin left to the Member States as to the patenting requirements	
a) Novelty, inventive step and industrial application	
aa) Novelty	
bb) Inventive step	
cc) Industrial application	
b) Enabling disclosure	
c) Disclosure of origin and proof of prior informed consent requirements	37
4. Margin left to the Member States with respect to the rights conferred, in particular by	
Art. 28(1)(b)	
a) Overview	
b) Conflict between Art. 27(3)(b) and Art. 28(1)(b)?	
c) Product directly obtained by a non-biological or microbiological process	
5. Exceptions and other use without authorization of the right holder	42
a) Limited exceptions provision	
b) Compulsory licences	44
III. The revision of Art. 27(3)(b) of the TRIPS Agreement	
IV. Conclusions of part A	47
B. OBLIGATIONS UNDER THE INTERNATIONAL INSTRUMENTS ON PLANT	
GENETIC RESOURCES	48
I. The FAO International Undertaking and its agreed interpretation	

II. The Convention on Biological Diversity	51
Objectives and coverage	51
2. Sovereign rights of States over their biological resources	53
3. Prior informed consent and benefit sharing	54
a) Principles	
b) Prior informed consent as patenting requirement	
III. The International Treaty on Plant Genetic Resources for Food and Agriculture	· 57
1. Farmers' rights	58
2. The Multilateral System of Access and Benefit Sharing	59
a) Coverage	59
b) Conditions of access	
c) Benefit sharing	
IV. Conclusions of part B	64
C. CONCLUSIONS AND OUTLOOK	
CHAPTER 3: THE EUROPEAN SYSTEM OF IP PROTECTION FOR P	LANT
VARIETIES AND PLANT RELATED BIOTECHNOLOGY INVENTION	NS 69
A THE BY AND DREEDERS DIGHTS (DDDS) SYSTEM DASED ON THE LIBOR	
A. THE PLANT BREEDERS' RIGHTS (PBRS) SYSTEM BASED ON THE UPOV CONVENTIONS	70
I. Motives for the introduction of a special form of protection for plant varieties	
1. Unsuitability of patenting requirements	
a) Living organisms as inventions	72
b) Inventive step of conventionally bred varieties	
c) Impossibility of description and non-reproducibility	
2. Unsuitability of the scope of patent protection and the rights conferred	
a) The principle of dependence	76
b) Farm-saved seed	
c) "Monopolies on food"	
3. Validity of these arguments today	
a) Patenting requirements	78
b) Scope of patent protection and rights conferred	80
c) Conclusion	80
II. Protectable subject matter: Plant varieties	
Definition of plant variety	
2. Limitation to certain genera and species under the 1978 Act	
III. Requirements for protection	
1. Distinctness	
a) Definition	
b) Criticism of the low threshold for protection	
c) The role of chemical and DNA characteristics	87
d) The reproach of facilitating "biopiracy"	
2. Commercial novelty	
3. Uniformity	
b) Criticism	
4. Stability	
a) Definition	
b) Criticism	
5. Examination of the application	
IV. Scope of the rights conferred	
1. Extent of rights and farmers' privilege	94
a) UPOV 1978 Act	
b) Persisting appropriability problems	94
a) LIDOV 1001 A at	

Breeders' exemption and essentially derived varieties	98
a) UPOV 1978 Act	98
b) Plagiarized varieties and genetic engineering	99
c) UPOV 1991 Act	
d) Implementation difficulties with respect to the concept of "essential derivation"	103
3. Restrictions for reasons of public interest	104
V. Appreciation of the PBRs system by stakeholders	104
1. As protection mechanism for plant varieties	105
2. As protection mechanism for plant related biotechnological inventions	
a) Background: Loopholes in the protection by PBRs	108
b) Balancing access to plant material and protection needs	109
c) The relationship between right holders and farmers	
3. Conclusion	111
VI. Conclusions of part A	112
B. PROTECTION OF PLANT RELATED INVENTIONS BY PATENTS	113
I. Concerns expressed with respect to patents for biological material	
1. Patenting of genes in their natural state and of plants already available to farmers a	
breeders	
2. Concerns about undermining the breeders' exemption	116
3. Patenting products of automatised genome sequencing	116
4. Overly broad patent claims	
a) Absolute product protection for DNA molecules	117
b) Patent protection for plants defined by characteristics obtainable by alternative	
approaches	118
5. Implications for farmers	
6. Biopiracy	
II. Patentable subject matter: Invention	120
Examples of claimed subject matter	
2. A priori patentability of biological material	
Demarcation between invention and discovery	
a) Solution to a technical problem	
b) Patentability of biological material in its original state	
c) Absolute product protection for DNA sequences	
III. Exceptions to patentability	
Inventions contrary to "ordre public" and morality	
a) Case by case assessment of ethical and environmental issues	
b) The concept of morality applied to genetic engineering	
c) The concept of ordre public applied to genetic engineering	
2. Exclusion of plant varieties	
a) Claims directed to plant varieties	
b) Claims to plants, embracing but not individually claiming plant varieties	133
c) Genetic components of plants	
d) Plant cells	
3. Exclusion of essentially biological processes	
4. Exception to the exception: Microbiological processes and products thereof	
5. Summary	
IV. Patenting requirements	
1. Industrial applicability	
a) Indication of a function	
b) Required technical content of applications	
2. Novelty	
a) Defining the state of the art	
aa) "Making available"	
nni "To the public"	144

b) Naturally occurring material	
c) Relationship of partial gene sequences and full-length gene	147
3. Inventive step	148
a) Reasonable expectation of success	149
b) Theoretical anticipation in prior art	
c) Claims merely formulating the objective technical problem to be solved	
d) Inventiveness of gene sequences	
e) Inventiveness of proteins	
4. Sufficiency of disclosure, support by description and clarity	
a) The ratio of the requirements of sufficient disclosure and of support by the description	
b) The extent to which the invention must be reproducible	
c) Anticipation of the technical effect at the theoretical level in prior art	
d) Defining the invention in functional terms	163
e) Deposit of living material	165
V. Scope of protection and of rights conferred	
1. Types of infringing activity	
a) General rules	
b) Application in the area of plant biotechnology	167
aa) Innocent infringement by farmers	167
bb) Use of the genetic background of transgenic plant varieties	
2. Extent of protection conferred	
a) The role of the claims	
b) Art. 69 EPC	
c) EC Biotechnology Directive	
aa) Inclusion of the progeny of self-reproducing material	
bb) Extension of protection conferred by a process patent	171
cc) Extension of protection to all material in which the product is incorporated	
dd) Overlapping DNA sequences	172
3. Limitations of and exceptions to the rights conferred by a patent	
a) Exhaustion	
b) Prior use	
c) Acts done privately for non-commercial purposes	
d) Experimental use exemption	
e) Farmers' privilege under the EC Biotechnology Directive	176
f) Compulsory cross-licensing	
VI. Conclusions of part B	
C. CHAPTER CONCLUSIONS	179
CHAPTER 4: ECONOMIC THEORY OF IPRS AND EMPIRICAL EVIDEN	CE
CHAFTER 4. ECONOMIC THEORY OF IFRS AND EMPIRICAL EVIDENCE.	
A. ECONOMIC THEORY OF IPRS	184
I. Intended economic effects	
1. Incentive for innovation	184
a) The appropriability problem of public goods	
b) Public good features of plant related biotechnological innovations and plant varieties	185
c) Objections against the "innovation inducement" rationale	187
d) Alternative public policy interventions	188
e) Degrees of appropriability depending on the shape of seed IP laws	189
2. Dissemination of technology	
3. Regulation of research allocation	
II. Economic tensions inherent in IP protection	
The tension between innovators and consumers	
2. The tension between first and second-generation inventors	194

3. Models defining optimal levels of patent length and breadth	
4. Conclusions	
III. Economic models assessing the effects of IPRs in developing countries	197
Static welfare analysis	
Dynamic welfare analysis	
3. Conclusions	
B. EMPIRICAL EVIDENCE	
I. Impact studies on patent protection	201
1. Innovative activity	
a) Company views on appropriability of innovations	
b) Domestic research & development (R&D)	
2. Economic growth	
3. Trade	
4. Foreign direct investment (FDI) and technology transfer	207
5. Consumer welfare	
6. Firm concentration	
7. Dissemination of scientific information and follow-on R&D	
8. Conclusions	
II. Empirical studies on the impact of plant variety protection	
1. Impact on R&D	215
a) US studies carried out in the early 1980s	
b) Later US studies	218
c) Evidence from other industrialized countries	219
d) Evidence from developing countries	
3. Firm and market concentration.	
a) Firm concentration	
b) Seed market shares	
4. Implications for farmers	
a) Evidence from the US.	
b) Evidence from developing countries	
5. Impact on information flows and germplasm exchange	
6. Impact on genetic diversity	
7. Conclusions	
C. CHAPTER CONCLUSIONS	220
CHAPTER 5: PRESENT STATUS OF THE INDIAN SEED SECTOR A	ND
FUTURE CHALLENGES	231
A. AGRICULTURAL POLICY IN THE LAST DECADES	231
I. Introduction of yield-raising new seed and fertiliser technology	
II. Development of the Indian seed industry	
Development of the public sector seed industry	
2. Decentralization of seed production	
3. Liberalisation policy	
B. CURRENT STRUCTURE OF THE SEED SECTOR	
I. Informal sector	
Informal sector I. Importance of the informal seed supply system	
Sources of informal seed supply	
Sources of informal seed supply Types of transactions involved	
4. Types of varieties covered	242
II. Formal sector	
1. Varietal development	
a) Public sector	

b) Private sector	245
2. Seed production.	250
a) Public sector	250
b) Private sector	251
3. Seed distribution	253
C. FUTURE CHALLENGES AND STRATEGIES	253
I. Necessity of annual increase in productivity	253
II. The 9th and 10th Five Year Plans give important role to input intensive agriculture	255
III. Limits of high input technology	
1. Environmental costs	
2. Regional limits of the Green Revolution	257
3. Social disparities	
IV. Strategies to overcome these limits	
1. Greater research emphasis on rainfed agriculture and poor man's crops	
Enhanced location-specific research	
3. Possibilities and limits of traditional agricultural techniques and landraces	
a) Advantages of diversity in marginal environments	
b) Value of landraces in modern crop breeding	263
c) Complementarity of in situ and ex situ conservation of crop resources	
Farmer participatory research	
5. Role of recombinant DNA technology in increasing productivity in a sustainable way	267
a) Potential of genetically modified crops	
b) Risks of genetically modified crops	269
aa) Parallels and differences between conventional and genetic engineering methods.	269
bb) Health risks.	269
cc) Environmental impact of genetically modified crops	
c) Attitude of the Indian public and stakeholders towards biotechnology	
6. Conclusions	
V. Need for increased private sector participation	
1. Shortcomings of public R&D	
2. Financial constraints	
D. CHAPTER CONCLUSIONS	282
CHAPTER 6: THE DEBATE ON POTENTIAL IMPACTS OF PLANT	
RELATED IPRS ON THE SEED SECTOR IN INDIA2	285
A. IMPACT ON THE PRIVATE SECTOR SEED AND PLANT BIOTECHNOLOGY	
INDUSTRY	
I. Increasing private investment in R&D	
Probable limits of private sector involvement	
a) Self-pollinated crops	
b) Small farming conditions and high potential rainfed areas	289
c) Marginal and heterogeneous environments	
d) Low-input agriculture	
e) Conclusion	
2. Incentive for local R&D?	
a) Patents	
aa) Increased FDI, technology transfer and local R&D of multinational corporations.	
bb) Balancing benefits and constraints for domestic firms	
cc) Need for a sector specific analysis	
b) Plant breeders' rights	
c) Conclusions	
II. Impact on knowledge dissemination and germplasm exchange	
Impact of patent protection	
a) Constraints created by patent rights	

b) Positive effect on technology transfer	
2. Impact of plant variety protection	
a) Impediment to free flow of germplasm?	300
b) Access to elite material and advanced technology from abroad	301
3. Conclusion	
III. Impact on seed industry structure	
a) Recent developments in the plant biotechnology industry in India	
b) Potential future development	304
Impact of plant breeders' rights	
3. Conclusion	
IV. Conclusion of part A	
B. IMPACT ON PUBLIC SECTOR SEED ORGANISATIONS	307
I. Patents	
Risk of being priced out of the market for proprietary technology	
2. Constraint to reorientate public sector R&D?	308
3. Need for a sector specific analysis	309
II. Plant breeders' rights	
1. Plant breeders' rights as means for rising funds	309
2. Possibility of focus on specific areas	310
III. Conclusion of part B	311
C. TECHNOLOGICAL CAPACITY OF THE INDIAN CROP BIOTECHNOLOGY	
SECTOR	
I. Research output	
II. Research input constraints	
1. Research funding	314
a) Public sector funding	212
2. Manpower.	
III. Views of experts on Indian biotechnology capacity	320
IV. Conclusions	321
D. IMPLICATIONS FOR FARMERS	
I. Restrictions on the rights of farmers to use, save, exchange, share, and sell seeds	322
1. Importance and characteristics of the informal sector	
Activities and varieties concerned by plant variety protection	
a) Legal scenarios	324
b) Types of activities concerned	325
c) Types of germplasm concerned	
3. Would exempting merely small farmers be a solution?	
4. Conclusion.	
II. Rise of seed prices	
1. Plant breeders' rights	
2. Patents	
E. EROSION OF GENETIC RESOURCES	
F. CONCLUSIONS	333
CHAPTER 7: IP PROTECTION FOR FARMERS' VARIETIES AND RELATED TRADITIONAL KNOWLEDGE	225
A. THE GENERAL PROBLEMATIC OF INTELLECTUAL PROPERTY PROTECT	
FOR TRADITIONAL KNOWLEDGE	
D DOLLOV OD LECTIVES	

I. Needs and expectations of farmer-breeders	
1. Recognition	338
2. Protection against misappropriation of germplasm or TK in the public domain	339
a) Misappropriation by claiming unmodified TK and farmers' varieties	340
b) "Misappropriation" by claiming innovations based on TK and farmers' varieties	
3. Benefit sharing	343
4. Control over use of traditional knowledge and germplasm	343
5. Relationship between farmer-innovators and their fellow farmers II. Current "market" for landrace germplasm in the formal sector	
III. Conclusions of part B	350
C. PRINCIPAL FEATURES OF FARMERS' VARIETIES AND CROP MANAGEMI PRACTICES	
I. Crop development practices	
Selection and hybridisation strategies	
a) Maintenance	
b) Hybridisation	
Individual and community knowledge, new and traditional practices	
II. Characteristics of farmers' varieties	
1. Genetic and phenotypic constitution and evolution of populations used by farmers	357
a) Genetic structure of these populations	357
aa) Outcrossing species	
bb) Inbreeding species	
b) The farmers' concept of variety based on the phenotype	358
2. Individual and community development of varieties	360
III. Conclusions of part C	
D. PROTECTION OF FARMERS' VARIETIES AND GRASSROOT BREEDING PRACTICES BY EXISTING IP PROTECTION SYSTEMS	
I. Protection of farmers' varieties by PBRs	
1. Requirements for protection	362
Requirements for protection a) Variety	362
Requirements for protection a) Variety b) DUS testing	362 362
Requirements for protection a) Variety b) DUS testing	362 362 363
Requirements for protection a) Variety b) DUS testing	362 363 363 364
1. Requirements for protection a) Variety b) DUS testing	362 363 363 364 365
1. Requirements for protection a) Variety b) DUS testing aa) UPOV standards bb) Application to farmers' varieties of self-pollinated crops cc) Application to farmers' varieties of cross-pollinated crops c) Commercial novelty	362 363 363 364 365
1. Requirements for protection a) Variety b) DUS testing aa) UPOV standards bb) Application to farmers' varieties of self-pollinated crops cc) Application to farmers' varieties of cross-pollinated crops c) Commercial novelty 2. Right-holder	362 363 363 364 365 367
1. Requirements for protection a) Variety b) DUS testing aa) UPOV standards bb) Application to farmers' varieties of self-pollinated crops cc) Application to farmers' varieties of cross-pollinated crops c) Commercial novelty. 2. Right-holder 3. Scope of rights conferred	362 363 363 365 367 368
1. Requirements for protection a) Variety b) DUS testing	362 363 363 364 367 367 368
1. Requirements for protection a) Variety b) DUS testing	362 363 363 365 367 367 368 368 368
1. Requirements for protection a) Variety b) DUS testing	362363363364365367368368369369
1. Requirements for protection a) Variety b) DUS testing	362363363364365367368368369369
1. Requirements for protection a) Variety b) DUS testing aa) UPOV standards bb) Application to farmers' varieties of self-pollinated crops cc) Application to farmers' varieties of cross-pollinated crops c) Commercial novelty 2. Right-holder 3. Scope of rights conferred a) In relation to formal sector breeders b) In relation to fellow farmers 4. Duration of protection 5. Procedural issues, enforcement 6. Conclusions	362 363 363 364 365 367 368 369 370 370 370
1. Requirements for protection a) Variety b) DUS testing aa) UPOV standards bb) Application to farmers' varieties of self-pollinated crops cc) Application to farmers' varieties of cross-pollinated crops c) Commercial novelty 2. Right-holder 3. Scope of rights conferred a) In relation to formal sector breeders b) In relation to fellow farmers 4. Duration of protection 5. Procedural issues, enforcement 6. Conclusions II. Protection of plants and of grassroot breeding methods by patents	362 363 363 364 365 366 369 370 371 371
1. Requirements for protection a) Variety b) DUS testing aa) UPOV standards bb) Application to farmers' varieties of self-pollinated crops cc) Application to farmers' varieties of cross-pollinated crops c) Commercial novelty 2. Right-holder 3. Scope of rights conferred a) In relation to formal sector breeders b) In relation to fellow farmers 4. Duration of protection 5. Procedural issues, enforcement 6. Conclusions II. Protection of plants and of grassroot breeding methods by patents 1. Patenting requirements	362363363363364365367368368369370371371
1. Requirements for protection a) Variety b) DUS testing aa) UPOV standards bb) Application to farmers' varieties of self-pollinated crops cc) Application to farmers' varieties of cross-pollinated crops c) Commercial novelty. 2. Right-holder 3. Scope of rights conferred a) In relation to formal sector breeders b) In relation to fellow farmers 4. Duration of protection 5. Procedural issues, enforcement 6. Conclusions II. Protection of plants and of grassroot breeding methods by patents 1. Patenting requirements a) Invention	
1. Requirements for protection a) Variety	
1. Requirements for protection a) Variety b) DUS testing aa) UPOV standards bb) Application to farmers' varieties of self-pollinated crops cc) Application to farmers' varieties of cross-pollinated crops c) Commercial novelty 2. Right-holder 3. Scope of rights conferred a) In relation to formal sector breeders b) In relation to fellow farmers 4. Duration of protection 5. Procedural issues, enforcement 6. Conclusions II. Protection of plants and of grassroot breeding methods by patents 1. Patenting requirements a) Invention b) Industrial applicability c) Novelty d) Inventive step.	
1. Requirements for protection a) Variety b) DUS testing aa) UPOV standards bb) Application to farmers' varieties of self-pollinated crops cc) Application to farmers' varieties of cross-pollinated crops c) Commercial novelty 2. Right-holder 3. Scope of rights conferred a) In relation to formal sector breeders b) In relation to fellow farmers 4. Duration of protection 5. Procedural issues, enforcement 6. Conclusions II. Protection of plants and of grassroot breeding methods by patents 1. Patenting requirements a) Invention b) Industrial applicability c) Novelty d) Inventive step e) Sufficient description and enabling disclosure	
1. Requirements for protection a) Variety b) DUS testing	
1. Requirements for protection a) Variety b) DUS testing	
1. Requirements for protection a) Variety b) DUS testing aa) UPOV standards bb) Application to farmers' varieties of self-pollinated crops cc) Application to farmers' varieties of cross-pollinated crops c) Commercial novelty. 2. Right-holder 3. Scope of rights conferred a) In relation to formal sector breeders b) In relation to fellow farmers 4. Duration of protection 5. Procedural issues, enforcement 6. Conclusions II. Protection of plants and of grassroot breeding methods by patents 1. Patenting requirements a) Invention b) Industrial applicability c) Novelty d) Inventive step. e) Sufficient description and enabling disclosure 2. Right-holders 3. Scope of patent protection and of rights conferred a) In relation to fellow farmers	
1. Requirements for protection a) Variety b) DUS testing	

5. Procedural issues and enforcement	375
6. Conclusions	376
E. SUI GENERIS SYSTEM OF IP PROTECTION FOR FARMERS' GERMPLASM	AND
RELATED TK	
I. Possible types of subject matter and requirements of protection	377
1. Subject matter "variety"	377
a) Observations on the criterion "identifiability"	377
b) More stringent description versus broader rights	
c) Protecting a moving target	
d) Necessity of more input from specialists	370
2. Subject matter "plant characteristic"	291
a) Implications for the shape of the protection system	201
b) The problem of sufficiently describing the plant characteristic	201
3. Subject matter "knowledge about crop characteristics"	201
4. Subject matter "breeding method"	
5. Conclusions	
II. Right-holders	
1. Individuals, communities or the State?	
a) Pros and cons of allocating the rights to the State	
b) Pros and cons of vesting rights in communities rather than individuals	
2. Registration as pre-condition for the emergence of the right	
a) Subject matter "plant characteristic"	
b) Subject matter "farmers' variety"	
c) Registration procedure	
1. Protection of stable farmers' varieties	
a) Relationship between farmer-breeders and their fellow farmers	
b) Relationship between farmers and formal sector breeders	
aa) Exclusive rights to market the same variety and essentially derived varieties	
bb) General maintenance of the breeders' privilege	202
cc) Compensation for certain uses in breeding	
c) Duration	
2. Protection of plant characteristics	
a) Relationship between farmer-breeders and their fellow farmers	
b) Relationship between farmers and formal sector breeders	
bb) Entitlement to benefit sharing	
c) Duration	
IV. Enforcement	
F. CONCLUSIONS	398
CHAPTER 8: ANALYSIS OF THE INDIAN PLANT RELATED IPR	
	401
LEGISLATION	401
A. LEGISLATIVE HISTORY	402
I. Patent legislation	
II. Plant varieties and farmers' rights legislation	
B. PATENT PROTECTION FOR PLANT RELATED INVENTIONS	
I. The revised invention definition	
II. Exclusions from patentability	
1. Sec. 3 of the Patents Act, 1970	
2. Sec. 5 of the Patents Act, 1970	
S. Sec. 48(0) of the Patents Act, 1970	
III. Discussife of origin requirement	411

IV. Compulsory licensing and revocation	
V. Conclusions	
C. SALIENT FEATURES OF THE PROTECTION OF PLANT VARIETIES AND)
FARMERS' RIGHTS ACT (PPV&FR ACT)	414
I. Authorities administering the Act	415
II. PBRs protection for new varieties	
1. Requirements for protection	
a) Novelty, distinctness, uniformity, stability, variety denomination	
b) Registration procedure	
c) Registration of essentially derived varieties	
2. Rights conferred and limitations	
a) Rights conferred	
b) Research exemption	
c) Breeders' exemption	
d) Farmers' privilege	
e) Compulsory licensing	
III. Protection of farmers' rights	424
1. Rights of farmers as plant variety users	
a) Liability of breedersb) Innocent infringement	
Rights of farmers as developers and conservers of germplasm	
a) Plant variety protection for farmers' varieties	
aa) Persons entitled to registration	
bb) Protection requirements	
cc) Registration	
dd) Rights conferred	
b) Benefit-sharing mechanism	
aa) Overview	
bb) Gene Fund	
cc) Establishing the contribution	
IV. Appropriation of varieties in the public domain	
1. Overview	
2. Requirements for protection.	
a) Definition of extant variety	
b) Distinctness, uniformity, stability	
3. Registration	
4. Rights conferred	
V. Summary of part C	
D. UPOV-CONFORMITY AND COMPLIANCE WITH INTERNATIONAL	
	425
OBLIGATIONS	
I. Conformity of the PPV&FR Act with the standards of the UPOV 1978 Act 1. Distinctness requirement	438
Brown-bag sales by farmers	438
Brown-bag sales by farmers. Benefit sharing	
a) The principle	
b) Requirement to indicate the pedigree, especially the use and origin of farmers	
b) Requirement to indicate the pedigree, especially the use and origin of farmers	
4. Compulsory licensing	
Compulsory licensing Conclusion	444
II. Conformity of the PPV&FR Act and the Indian Patents Act with the standard	
TRIPS Agreement	
1. Effective sui generis system	
a) Limitation of protection to certain genera and species	445
b) Disclosure of origin requirements	445
,	

c) Brown-bag sales by farmers	446
2. Compliance of patent protection for plant related inventions with TRIPS minimum	
standardsstandards	447
a) Patentable subject matter	
b) Derived product protection for products obtained directly by a protected process	
c) Disclosure of origin requirement	
d) Compulsory licensing	
III. Conformity with the standards of the PGRFA Treaty	448
E. CONCLUSIONS	449
CHAPTER 9: CONCLUSIONS	451
A. PROTECTION FOR FORMAL SECTOR VARIETIES	451
I. Need for and limits of private sector R&D	451
II. PBRs protection: In principle the suitable form of protection	452
III. Scope of the farmers' privilege	
B. PROTECTION FOR FARMERS' PLANT GENETIC RESOURCES	
I. Need for in situ crop conservation and improvement	
II. Possible types of subject matter and scope of protection	
III. Right holders	455
C. PROTECTION FOR PLANT RELATED BIOTECHNOLOGICAL INVENTIONS	455
I. Need for biotechnology R&D	455
II. Pros and cons of product patents	455
III. Unclear level of biotechnological competence	456
IV. Modulated patent protection	456
D. OUTLOOK	457
GLOSSARY	459
LIST OF CITED EXPERTS AND STAKEHOLDERS CONSULTED ORAL	LY
OR IN WRITING	465
REFERENCES	467

CHAPTER 1: INTRODUCTION

A primary aim of Indian agricultural policy is food security. To keep pace with the annual growth rate of population, which amounted to an average of 2.1% annually in the last decade, India has to increase its agricultural production steadily. Since a high percentage of the country's geographical area is already under cultivation and possibilities of area expansion are minimal, increases in agricultural production must result from improvement of agricultural productivity per unit of land.³ A crucial input for attaining sustained growth of agricultural production is seed. According to some estimations more than half of the real productivity growth in developing country agricultures can be attributed to crop improvement.⁴

In the international and Indian discussion on how to achieve growth of agricultural production, sustainable development, and increase of income for small and marginal farmers, three types of crop genetic resources are cited which could potentially play a crucial role in reaching these goals in the future:

- (1) modern high yielding varieties (HYV), a variety being defined as population of plants which are largely the same in their characteristics (resulting from a given genotype or combination of genotypes) and remain the same within specific tolerances after every propagation.⁵
- (2) genetically modified plants, i.e. plants modified in their genetic structure by using recombinant DNA technology, and
- (3) farmers' varieties or landraces, which can be defined as "heterogeneous crop populations that humans deliberately cultivate [and] that are not products of modern plant breeding or subject to purifying selection."

Behind these three types of crop germplasm⁷ stand different types of breeding activities in the largest sense of the term with very different technical and economical characteristics and carried out by different stakeholders8: HYV are developed by a specialized breeding industry, whose work is principally based on selection and crossing steps but which now uses highly technical and sophisticated tools to control the genetic structure of the resulting populations. Landraces are not, as suggested by early authors in the first half of the last century, the result of natural adaptation to the

⁵ A similar definition is used, e.g., by the Enlarged Board of Appeal of the EPOin its decision G 1/98, at point 3.1 of the reasons. For more details on the plant variety definition, see below chapter 3, A.II.1, at 81.

⁷ The term "crop germplasm" can be defined as an array of plant materials, such as landraces, improved varieties or wild relatives, that serves as a basis for crop improvement.

¹ See GOVERNMENT OF INDIA, Planning Commission, 9th FIVE YEAR PLAN (1997-2002), at para. 4.1.20. See further GOVERNMENT OF INDIA, Planning Commission, 10th FIVE YEAR PLAN (2002-2007), at para. 5.1.2.

See GOVERNMENT OF INDIA (2003), table 2.3: "Population, Growth Rate – 2001 (Provisional)".

³ See SIDHU/SIDHU (1994), at 77; GOVERNMENT OF INDIA (1997-2002), at para. 4.1.67.

⁴ See EVENSON (2002), at 7.

⁶ See BROWN (2000), at 29.

⁸ Stakeholders are understood in this paper as persons or entities with a stake in a particular issue or resource, e.g. in the IP context producers and users of knowledge.

local environment,⁹ but the result of a dynamic interaction between farmers and their crops.¹⁰ For this reason, in the following, the term "farmers' varieties" will be preferred. Finally, genetically modified plants are developed by genetic engineers. The result of their scientific work is a modified plant, not a marketable plant variety.

The development and/or conservation of the above three components of crop genetic resources will, among other things, ¹¹ depend on economic incentives to pursue these activities. Yet, improvers of crop germplasm face a significant problem when they attempt to appropriate part of the added value of their improved crops. ¹² Since plants are capable of self-reproduction and transfer improved characteristics from one generation to the next there is generally no need for the users of the plant innovation to have recourse to the developer for supply. At the same time, the economic return from the sale of the first generation of plant material may not provide sufficient incentive for the private seed developer to invest time and resources in crop improvement. The idea of intellectual property rights (IPRs)¹³ in crop germplasm is to grant germplasm improvers an exclusive right of exploitation in order to secure a reasonable return on their investments. ¹⁴ This is one of the "classical" arguments that have lead to the introduction of plant breeders' rights (PBRs) for plant varieties and patents for genetically modified crops. The same line of thinking is now also increasingly applied to farmers' varieties. ¹⁵

For this reason, with respect to all three types of crop germplasm, the introduction of IPRs is discussed as possible part of the solution to ensure increased and yet sustainable agricultural production. Exclusive rights for breeders of modern varieties,

⁹ See the references given by HALEWOOD et al. (DISCUSSION PAPER of 2003), at 4.

_

This interaction will be described in detail in chapter 7.

Another important element is legislation on seed quality and registration which may, by imposing registration and/or high purity standards on all commercialized seeds, seriously affect the dissemination of farmers' varieties and more generally seed supply by farmers. Although this issue is closely linked to the development and/or conservation of the above three components of crop genetic resources it will not be discussed in detail in this book. The Seed Bill 2004 introduced in the Rajya Sabha on 9 December 2004 is rather unclear, highly controversial and would, if interpreted in a certain way, contradict the spirit of the Protection of Plant Varieties and Farmers' Rights Act. The Bill is available at http://agricoop.nic.in/seeds/seeds_bill.htm. A few aspects of this Bill will be mentioned below in chapter 8. However, a detailed analysis of this piece of legislation which, if passed by Parliament, could have a tremendous impact on the seed sector, would go beyond the scope of this book.

¹² This problem will be discussed in detail in chapter 4.

¹³ Intellectual property rights can be defined as rights and interests in intangible assets susceptible of being used in commerce.

¹⁴ On the 'Need for Legal Protection of Plant Varieties' see UPOV, The UPOV System of Plant Variety Protection, at 4 of 13, available at http://www.upov.org/en/about/upov_system.htm, last visited on 10.03.03.

¹⁵ According to the Commission on Plant Genetic Resources (CPGR), "the major factor driving genetic erosion is that traditional farmers, their communities and countries, who develop and conserve agro-biodiversity, are generating externalities as providers of a 'public good', that is, they are producing global values for which they obtain no return, and are therefore without incentive to continue them: without appropriate and urgent solutions to this paradox, the loss of agro-biodiversity will accelerate, with irreversible, serious global consequences." See FAO Doc. CPGR-Ex1/94/Inf. 1 (Sept. 1994), at 21, para. 34, as quoted by GIRSBERGER (1999), at 68.

for farmers conserving and improving landraces, and for plant genetic engineers could provide an incentive for increased research and development (R&D) and local conservation and breeding efforts.

On the other hand, critics point out that granting exclusive rights implies imposing restrictions on the use of the relevant germplasm. This necessarily leads to welfare losses which have to be balanced against the benefits of intellectual property (IP) protection. These welfare losses have particular weight in technology imitating countries where the positive dynamic effects of IP on R&D can be partly replaced by technology spillovers from industrialized countries by imitation. Opponents to IP protection in developing countries emphasize that exclusive rights could allow multinational corporations (MNCs) to dominate the seed market and hamper the rising domestic industry which is scaling up its R&D skills by adapting foreign technology. They further fear that these rights could hinder the diffusion of new technology and endanger the existence of small farmers depending on farmer-to-farmer seed sales.

Whereas in Europe the shape of plant related IP legislation is mainly debated in the specialized literature, in India the implementation of Art. 27 of the TRIPS Agreement has been accompanied by a heated public debate. Protest rallies have repeatedly mobilised hundreds of thousands of farmers. In order to understand the passionate controversy about seed related IPR one has to keep in mind the important role agriculture plays in the Indian economy and the crucial role that seed plays in the life of Indian farmers. The agriculture sector has still a vital place in the economic development of India. Although the share of agriculture, including allied sectors of forestry & logging and fishing, in the GDP has declined from 39% in 1983 to 25% in 1999-2000, 16 compared with industrialized country economies this share is still significant. Similarly, yet at a slower rate, the share of agriculture in total employment declined from 63% to 59%. ¹⁷ On an individual level, for many Indians the availability of seed and its performance is still a question of survival. India has overcome its import dependency in the last decades and can now claim to be self-sufficient. Nevertheless, this success of agricultural policy is still very fragile in view of population growth and natural resource degradation. ¹⁸ Therefore any new policy in the agricultural sector raises concerns about its implications for food security. Any legislation that impacts agricultural development has to be particularly carefully designed.

Experts and commentators in India further criticize that the industrialized country models of plant related IP protection only protect crop improvement activities that take place in the formal sector, i.e. that of specialized plant breeders and of plant genetic engineers.¹⁹ They do not recognize and reward the contributions to modern plant

¹⁶ See GOVERNMENT OF INDIA (2004), at 20.

¹⁷ See id., at 124. The total economically active population is estminated at 451 million, 267 million in agriculture.

¹⁸ See below chapter 5, C.I und III.1.

¹⁹ Formal sector research/crop improvement/breeding is understood here as research that takes place in public academic or other scientific institutions, as well as in corporate research laboratories, greenhouses, test fields, and is carried out by specialized researchers. It is embedded in a scientific

breeding of actors in the informal sector, i.e. of farmers who enhance and conserve crop genetic diversity. There is indeed a permanent exchange of germplasm between the three groups of stakeholders involved in the crop improvement activities described above. Formal sector breeders depend for their work on the availability of genetic diversity, which will stem either from other HYVs, from farmers' varieties or from genetically modified plants. Farmers, seen as one group, 20 are providers of genetic diversity and users of modern crop technology. Finally, genetic engineers use inter alia genetic components of farmers' varieties and depend on breeders for reaching the end-users of their invention, since the outcome of a biotechnological process is not yet a stable heterogeneous high-yielding plant population. All three groups of stakeholders are at some point users of germplasm improved by another group and at another point providers. "Classical" IP systems in industrial countries subject the use of new seed technology developed by the formal sector to certain restrictions, while the use of heterogeneous populations developed by farmers is free, as they do not meet the requirements of PBRs protection. This has led critics to speak of "one way subsidy". 21 But a careful differentiation between different shapes of IPR systems is necessary. Certain systems permit only a very limited scope for appropriation by formal sector breeders and leave the remaining benefits to farmers. It is indispensable to take a comprehensive approach and discuss costs and benefits for all three groups of different IP protection solutions for HYV, genetically modified crops, and farmers' varieties in order to find a balance between the different interests involved.

The following paper develops suggestions as to what shape a comprehensive system of crop related IP protection for India should take. In order to arrive at these suggestions, the following structure is adopted: Chapter 2 will highlight the international commitments, which may reduce the scope of action of the Indian legislature in the area of plant genetic resources. These obligations stem from the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)²² which obliges Member States to provide certain minimum standards of protection, from the Convention on Biological Diversity (CBD)²³, and from the International Treaty on Plant Genetic Resources for Food and Agriculture (PGFRA Treaty).²⁴ Chapter 3 will give an overview of the European system of plant related IP with its two alternative protection regimes, one for plant varieties, the other for plant related inventions. This

knowledge system which assumes that researchers have the potential to understand the processes of nature, to describe underlying causalities in theory and to harness theory to manipulate the environment. VAN DUSSELDORP/BOX (1993), at 22, term this the "voluntaristic worldview". In contrast, informal sector research takes place outside this organized environment and is not necessarily based on this voluntaristic wordview.

²⁰ Yet, the individual farmer who conserves traditional germplasm may not be the same as the farmer who uses modern seed technology.

²¹ See SWAMINATHAN (1995b), at 247.

²² Agreement on Trade Related Aspects of Intellectual Property Rights of 15 April 1994, available at http://www.wto.org/english/docs-e/legal-e/27-trips.doc, in force since 1 Januar 1995.

²³ Convention on Biological Diversity of 5 June 1992, available at

http://www.biodiv.org/convention/articles.asp, in force since 29 December 1993.

²⁴ International Treaty on Plant Genetic Resources for Food and Agriculture, approved through FAO Resolution 3/2001 of November 2001, available at http://www.fao.org/legal/TREATIES/033t-e.htm, in force since 29 June 2004.

chapter will thus permit analysing a system in operation which combines patent protection restricted to specific areas of plant related innovation with a protection system specifically adapted to plant varieties. In order to draw lessons from this experience for the Indian legislature, views of experts and stakeholders on the system will be presented. Chapter 4 will discuss the principal findings of the literature on economics with respect to the economic impacts of IP protection in order to provide the necessary background for later analysing the arguments set forward in the debate in India. Since the optimal design of IP legislation depends on the economic situation in a specific sector in a given country, chapter 5 will highlight the present status of the Indian seed sector and the future challenges that agricultural policy will have to respond to in this sector. The Indian debate on the potential impact of PBRs and patents on the seed sector in India will be analysed in chapter 6. Chapter 7 will review the possibilities and implications of protecting farmers' varieties by a sui generis IP system. Chapter 8 will outline the Indian legislation relating to IP protection for plant genetic resources. Finally, chapter 9 will submit suggestions for the main features of a suitable system of IP protection for plant genetic resources in India.

Before discussing the legal and economic dimensions of the present issue, it should be mentioned that the arguments set forward against PBRs and patents in the agricultural sector go beyond the questions of economic and social impact which are in the focus here. There is, for instance, a school of thought that believes that all knowledge related to agriculture and seed should be part of the public domain or be owned collectively by all Indians or all farming communities, because turning seeds and related knowledge into a commodity is contrary to the beliefs of the farming communities concerned.²⁵ Some examples of traditional customs and beliefs may illustrate this view:

"New seeds are first worshipped and then planted. The new crop is worshipped before being consumed. Both these festivals – planting and harvest – are celebrated in the fields and symbolize people's intimacy with nature. At the time of planting, the field is seen as mother; worshipping the field is a sign of gratitude towards the earth, who as mother feeds the millions of life forms who are her children. Festivals like *Ugadi*, *Ramanavami*, *Akshay Trateeya*, *Ekadashi Aluyana Amavase*, *Naga Panchami*, *Noolu Hunime*, *Ganesh Chaturthi*, *Rishi Panchami*, *Navratri*, *Deepavali*, *Rathasaptami*, *Tulsi Vivaha Campasruti* and *Bhoomi Puja* cannot be celebrated without religious ceremonies around the seed. [...] According to Hindu mythology, seed is a gift of Srushtikarta (Brahma, the creator), who created seeds in primordial times. [...] Seed is also considered and worshipped as Dhanalakshmi (the goddess of wealth)." ²⁶

This raises the questions how widely these practices are spread and to what extent these beliefs are perceived as contrary to any form of IP. These issues and related ethical considerations are beyond the scope of this paper. It is only obvious that within India itself different cultures are clashing. The heterogeneity of beliefs that exists

²⁵ See SHIVA (2001), at 69 et seq.

²⁶ See SHIVA (2001), at 70/71.

within India in this respect is certainly an immense challenge to the Indian legislator and may have influenced the assessment of political feasibility of certain solutions.