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A Comprehensive Plant Germplasm System

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This book is dedicated to my wife Beatriz.

Preface

The innovation and scientific and technical development of modern plant varieties (which are novel, distinct, uniform, and stable), including the development of beneficial microorganisms, the access to and use of plant genetic resources, and the development of biotechnological and biosafety inventions, are regulated at the international, regional, and national levels. This regulation is in the form of many treaties, conventions, protocols, international agreements, and other regional and domestic rules. This complex set of rules has resulted in challenges to make global interpretations, due to overlapping, gaps, ambiguities, contradictions, and lack of consistency. The big picture is even more complex, as a series of scientific developments applied in plant breeding in general—especially in gene-editing techniques—have rendered these international regulatory frameworks obsolete.

Feeding and providing energy to the world requires doubling agricultural production between 2010 and 2050. Attaining this goal demands a yearly 2.4% growth rate in the main crops. A series of studies and analyses from different sources point to the fact that the productive growth rate of the main crops is in a critical point at half that value.

Indicators show that with the current scenario the world is facing an imminent and growing agricultural crisis in a perfect Malthusian model, in which Boserup's speculation that past a critical point new agriculture forms evolve and innovation is stimulated might be wrong.

The claim in this study is that facts are interrelated. The complex set of regulations about the development of modern plant varieties and beneficial microorganisms is the *cause* affecting the access to and use of genetic resources, as well as the research and development in genetics and plant breeding. And the *effect* is the standstill in productivity growth, that is, the innovation rate.

The attempts of methods, ideas, and proposals to tackle the regulatory hassle have not proven to be effective so far. To a large extent, this has been due to a lack of understanding of the productive models which have led to the development of "Agriculture 4.0" with features never seen before and which requires adopting a

different regulatory paradigm in its broadest concept. The current "Agriculture 3.0" paradigm based on a set of separate regulatory tools does not seem to be the proper way to satisfy the demand in this new scenario.

Attempted solutions to these challenges based on game theory have also been unsuccessful. This work claims that this failure was due to resorting to models within a framework of a noncooperative, competitive, and mainly zero-sum game theory, without any consideration for the existing relationships between all players. Opposite to that, the proposal contained here is a solution based on applying a convex superadditive cooperative model of relationships among the three sectors or players—for this, it is necessary to design a system of balance and transfer of profits of participants.

Based on this, a "Comprehensive Plant Germplasm System" is introduced as a general proposal for all industries driving plant innovation, including heterogeneous plant varieties, microorganisms, biotechnological developments, genetic resources, and biosafety.

The system is a proposal of minimum contents for a binding international convention which would supersede all conventions, treaties, and other regional or domestic regulations covering native varieties and traditional developments, heterogeneous plant varieties, plant varieties, microorganisms, biotechnological inventions, plant-breeding resources, and biosafety regulation.

In short, the basic message of this book is about a comprehensive theory and proposal of intellectual property, biosafety, and business regulation covering any kind of germplasm.

The positive externality expected as a result of the application of the system is the recovery of productivity rates in crops and food biodiversity through the massive use of genetic resources and their application to the development of new living matter for feeding, while protecting the interests and rights of all players without exceptions at the same time.

In other words, this is a new paradigm based on the promotion of innovation for "Agriculture 4.0."

Buenos Aires, Argentina Miguel Angel Rapela

Acknowledgements

This book is the result of dozens of years of experience at the domestic and international levels, both in the private and the public sectors, in connection with plant innovation.

I have a huge debt of gratitude toward hundreds of colleagues and experts from universities, research centers, and seed companies all over the world. Aware that I am not mentioning countless institutions, I specifically wish to thank my colleagues at the Intellectual Property Committee and the Working Group on Plant Breeding and Innovation of the International Seed Federation for the opportunity to discuss many of the issues included in this work.

I would like to acknowledge Austral University and, particularly, its Intellectual Property Centre. With this contribution, the Centre is resuming the road as an institution generating ideas and projects with domestic and international significance, and I am personally proud of this.

I would also like to thank Dr. Andrés Sánchez Herrero and Dr. Gustavo Schotz, both professors at Austral University, Argentina, for their patience in reading the original text, their remarks and suggestions, in addition to the publishing assistance they offered.

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Abbreviations

AIR	Am I regulated? Voluntary system applied in the USA for the regulation of biotechnological products
BGs	Bonn Guidelines
BT	Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CPB	Cartagena Protocol on Biosafety
CRISPR-Cas9	Clustered regularly interspaced short palindromic repeats. Cas-9 are natural endonuclease enzymes which are always associated with CRISPR loci
DNA	Deoxyribonucleic acid
DSB	DNA double-strand break
DSI	Digital sequence information
EDV	Essentially derived variety
EPSPS	5′-Enolpyruvylshikimate-3-phosphate synthase
GATT	General Agreement on Tariffs and Trade
GMO	Genetically modified organism
HDR	Homology-directed repair
HPVs	Heterogeneous plant varieties
INDEL	DNA base insertions or deletions
IPRs	Intellectual property rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAS	Marker-assisted selection
MATs	Mutually agreed terms
NBTs	New breeding techniques
NHEJ	Non-homologous end joining
NP	Nagoya Protocol
ODM	Oligonucleotide-directed mutagenesis
OECD	Organisation for Economic Co-operation and Development

OP	Open procedure. The procedure to be applied to facilitate access to germplasm and fairly and equitably share the benefits derived from the use of such resources, on the basis of complementarity and mutual strengthening
PBRs	Plant breeder rights of the UPOV Acts
PCPIP	Paris Convention for the Protection of Industrial Property
PCT	Patent Cooperation Treaty
PGRs	Plant genetic resources
PIC	Prior Informed Consent
PLT	Patent Law Treaty
TALEN	Transcription activator-like effector nucleases. These are artificially created restriction endonuclease enzymes
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UPOV	International Union for the Protection of New Varieties of Plants
WTO	World Trade Organization
ZFN	Zinc finger nucleases with zinc fingers. These are artificially created restriction endonuclease enzymes