ECONOMIC IMPACT OF DISCLOSURE REQUIREMENTS IN PATENT APPLICATIONS FOR 'GENETIC RESOURCES'-BASED INNOVATION

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Contents

Executive Summary i

1 Introduction 1
1.1 The value of genetic resources 1
1.2 Access and Benefit Sharing (ABS) systems 3
1.3 Disclosure requirements 4
1.4 Research question and study scope 4

2 Study framework 4

3 General effects of Disclosure Requirements 5

4 Brazilian case 6
4.1 Introduction 6
4.2 Scope 7
4.3 Conclusions and recommendations 8

5 Indian case 9
5.1 Introduction 9
5.2 Scope 10
5.3 Conclusions and Recommendations 11

6 Conclusions and Recommendations 12

Annex 1: References 14

Annex 2: Summary ABS legislation 16

Annex 3: Overview of Interviewees 18

Annex 4: Origin crop species as documented in ITPGRFA 19

Annex 6: Trade balance of crop agriculture 20

Commissioned by IFPMA and Crop Life International

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ECONOMIC IMPACT OF DISCLOSURE REQUIREMENTS IN PATENT APPLICATIONS FOR 'GENETIC RESOURCES'-BASED INNOVATION

COMMISSIONED BY IFPMA AND CROP LIFE INTERNATIONAL

IFPMA and Crop Life International commissioned Steward Redqueen to explore the economic effects of disclosure requirements on actors in the 'genetic resources'-innovation chain. The study provides a generic overview of the effects and in-depth insights of case studies in Brazil and India.

EXECUTIVE SUMMARY

Genetic Resources (GRs) are a key source of numerous biotechnology innovations. These resources refer to valuable material of for example animals, medicinal plants and agricultural crops. History reveals that less than 1% of species have provided the basic resources for the development of all civilization thus far. Therefore, it is reasonable to expect that the unexplored GRs include a certain potential value. Uncertainty is a central characteristic of bioprospecting as it is rarely possible to predict which genes, species or ecosystems will become valuable in the future.[1]

Over the last decades, regulations have been developed that aim to improve the sustainable use of GRs to protect biodiversity, and support benefit sharing with countries of origin. These regulations are also referred to as Access-Benefit Sharing (ABS) systems. 'Convention on Biological Diversity' (CBD) of 1992 serves as starting point in many countries.[2] The more recent Nagoya protocol, a 2010 supplementary agreement to the CBD, is aimed to improve the fair and equitable sharing of benefits arising out of the utilization of genetic resources.[3]

ABS systems vary widely, although GR-rich countries tend to organize their systems more strictly and focus on acquiring an equitable share of the benefits related to products resulting from the use of GR.[4] Over the years, several governments introduced disclosure requirements (DRs) in the patent system as an extra component, allegedly to enhance ABS compliance.[5] This research focuses on:

- What are the socio-economic effects of DRs?
- Is the DR procedure the optimal checkpoint to assure ABS compliance?

DRs can relate to (i) the GR origin and/or source used in the invention, (ii) evidence of prior informed consent (PIC) on GR access, and (iii) evidence of a benefit-sharing agreement (MAT). Although it was discussed during the negotiations, the Nagoya protocol does not include a reference to DR as a checkpoint for ABS compliance. Supporters of DRs claim that it will reduce granting erroneous patents over GRs and will eventually increase benefits for local communities. Furthermore, they claim that securing ABS conditions in the patent system will increase transparency.

On the other hand, opponents expect that the alleged benefits will not outweigh the societal losses. These could affect government (enforcement costs) and biotech firms (R&D costs, delay and uncertainty), which could eventually lower the levels of new GR-based products and thus lower benefits for local GR-communities

[1] Beattie et al, 2006

[2] CBD 2010

[3] CISDL 2014

[4] Sumikura 2008; CISDL 2014

[5] WIPO, 2017

and end-consumers. The Brazilian and Indian case study highlight that disclosure requirements delay the patent application process (based on local GRs) by 1-4 years. Also, in India, only 63 out of 574 (11%) applications received permission to apply for a GR-based patent.[6] Sectors that are largely affected are the ones that make intensive use of both patents and GRs. These are for example the pharmaceutical sector and agriculture.[7]

Several public articles and interviews also highlighted that the combination of patents and GR implies a shortcoming of DRs as checkpoint per se, because many GR-based innovations do not involve a patent, e.g. FMCGs such as cosmetics. Therefore, DRs can only be a complete checkpoint in combination with other procedures. And, at the same time, many patented products do not reach the market. For these reasons, several interviewees involved in this research recommend an alternative checkpoint during the market authorization process of products.

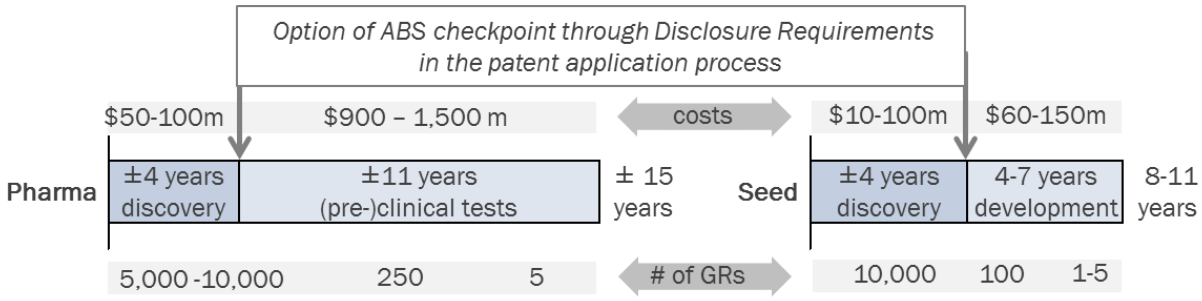

Exhibit summary: Examples of typical R&D cycles in pharma and agriculture[8]

DRs have a direct influence on the discovery phase of the R&D cycle. The length and costs vary widely per sector and innovation, but in seed and pharma it is on average 4 years within a cost range of $10m and $100m. These cycles require on average ≥ 5,000 genetic materials to come up with a single innovation (see Exhibit above).

Public research and interviews with Brazilian and Indian stakeholders indicate that DRs might increase R&D costs, with the main burden in the terms of extra delay and increased uncertainty. The uncertainty relates to unclear definitions of GRs (Brazil, India)[9] and to the fact that the content of the Disclosure Requirements is not verified by the IP authorities (Brazil, India). This provides more room for challenging patents on ABS conditions after approval. The extent of the DR-effects on R&D cycles depends largely on local market conditions and (efficiency of) ABS legislation.

Key takeaways Brazilian case: effects disclosure requirements

- In 2006, disclosure requirements were regulated by two separate resolutions of the biodiversity council (CGEN) and IP body (INPI), and involved several changes for GR-based patent applicants;
- During the first 10 years (2006-2016), DRs delayed patent applications from months to over 2 years, increased third party costs for GRs using businesses, and uncertainty after patent approval;
- The delay was mainly explained by the authorization number process managed by the Biodiversity Council (confirming disclosure of origin, PIC, MAT), which is required for patent applicants;

[6] Indian Patent Office, 2015

[7] Saez 2016; ICC 2011; Henninger 2009; Oxley 2006; Nair 2011

[8] Adams et al 2006; DiMasi et al 2016; Phillips McDougall 2016

[9] Prasad Oli 2009; Indian Habitat Center 2015; Sharma 2016; Remfry & Sagar 2015; Vadhera 2016

- New DR regulation implemented in 2015 is expected to limit the burden by an improved process and might clear procedures, but extra outsourcing for DR compliance and the uncertainty remain;
- An ABS checkpoint for GR-based products in the final development phase could be more effective, by capturing only products that reach the market including non-patented innovations.

Key takeaways Indian case: effects disclosure requirements

- After the 2005 Patent Act amendment, patent applicants faced stricter disclosure requirements for innovations based upon Indian genetic resources;
- Initially, the patent process was delayed with 4 years due the National Biodiversity Authority permission process required for applicants, and recently seemed to be improved to 1–1.5 years;
- Interviewees also indicated the complexity of having two separate bodies involved, and the uncertainty created because of the unclear and inconsistent definitions.

ECONOMIC IMPACT OF DISCLOSURE REQUIREMENTS IN PATENT APPLICATIONS FOR 'GENETIC RESOURCES'-BASED INNOVATION

1 INTRODUCTION

1.1 The value of genetic resources

Genetic Resources (GRs) are a key source of numerous biotechnology innovations. GRs refer to valuable material of for example plants, animals or micro-organisms, or parts thereof. These GRs are spread across the globe, with the largest documented resources available in Brazil (7.5%) and Columbia (6.9%), see Exhibit 1. In total, there are about 5 to 30 million GRs, while only 2 million have been documented so far.[10]

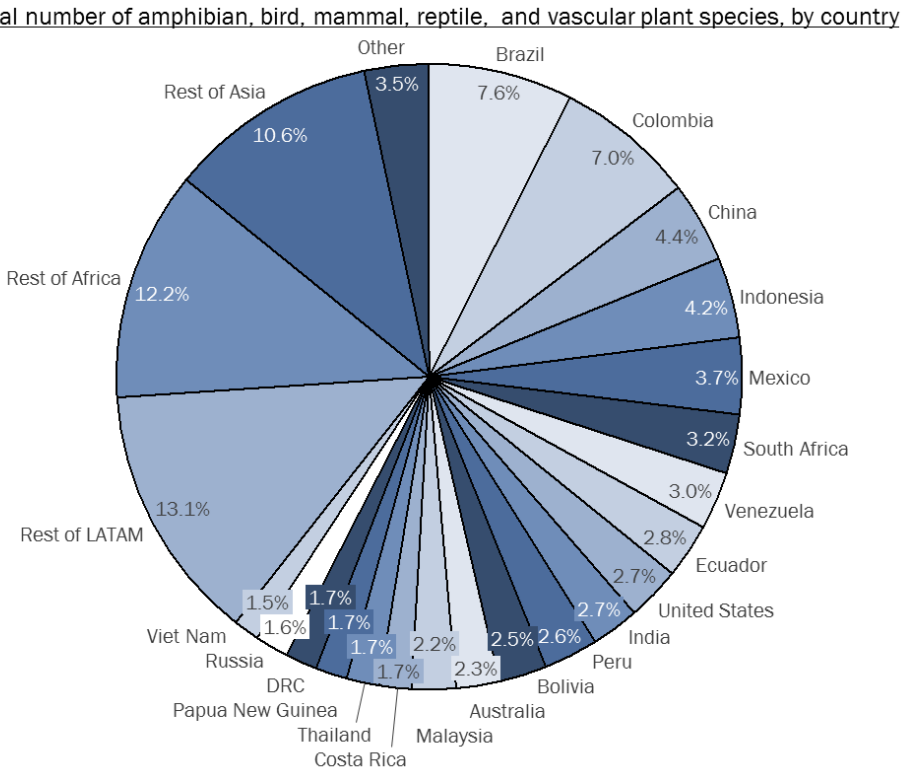

Exhibit 1: Total number of amphibian, bird, mammal, reptile, and vascular plant species by country[11]

The use of genetic resources for biotechnology innovations provide a much different view. Exhibit 2 provides an overview of the origin of species in biotech patents as an indication of genetic resources use. Here, most GRs in patents originate from Western countries (EU, US, Australia, Japan, New-Zealand), and indicates that these countries make more productive use of their GRs while they have relatively less available. Note that inventions resulting from the use of GRs can be patented, but not the genetic resources itself.

[10] Beattie 2016

[11] UNEP 2004

GRs as input for innovation cycles are collected through bioprospecting and gene banks. Bioprospecting is the exploration of biodiversity on the ground, and is carried out by many industries, e.g. pharmaceuticals, crop protection, cosmetics, manufacturing, agriculture. History reveals that less than 1% of species have provided the basic resources for the development of all civilization thus far.[12] There is still a potential value in unexplored or unused GR, hence the need for rules to enable effective access and sustainable use of GR. Uncertainty is a central characteristic of in the use of GRs as it is not possible to predict which genes, species or ecosystems will become valuable in the future.

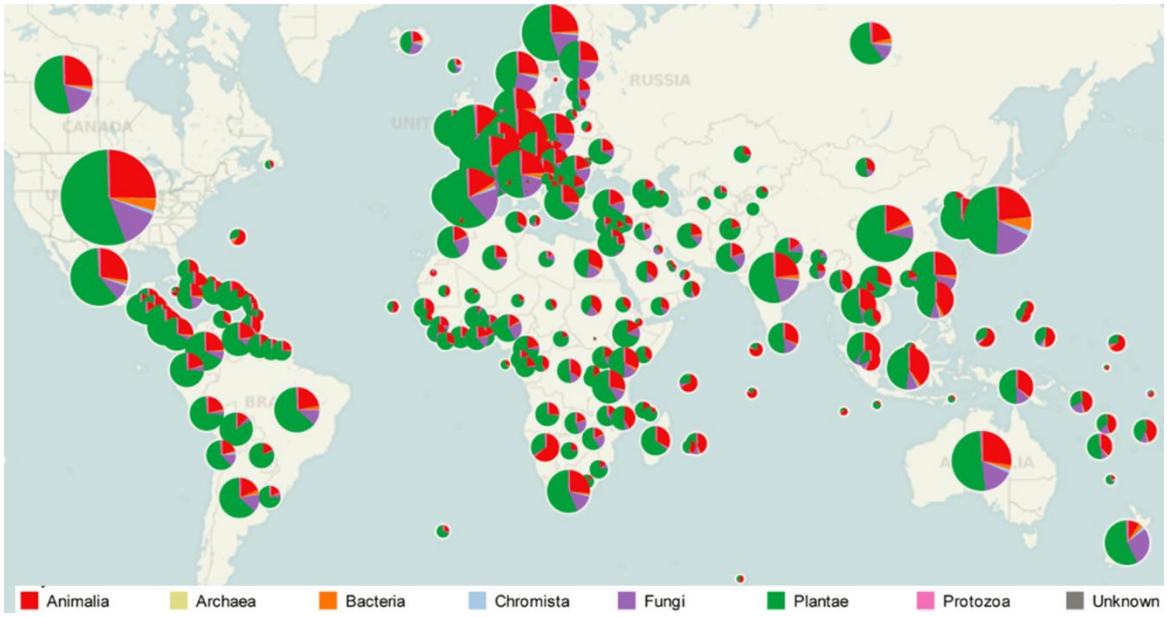

Exhibit 2: Global distribution of species origin in patents[13]

As GRs and its use are distributed among many regions, each country depends on products that are originally based on 'foreign' GRs. An example is the origin of 81 key crops[14], see Annex 3, where the origination and its consumption are scattered across the globe. Exhibit 3 provides an example of the crop trade balance based on two different lenses: the conventional one related to local production, and the alternative one related to GR origin. It highlights that within Brazil, a country recognized for its large crop trade surplus, many locally produced crops relate to GRs with non-Brazilian origin.

[12] Beattie 2006

[13] Oldham P, Hall S, Forero O (2013) Biological Diversity in the Patent System. PLoS ONE 8(11)

[14] ITPGRFA 2001

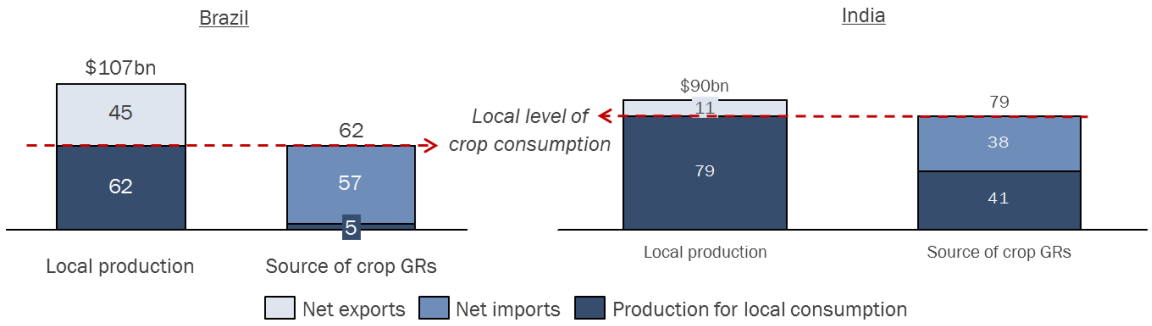

Exhibit 3: Trade balance crop agriculture in Brazil (left, 2014) and India (right, 2013) based on actual production and crop's GR origin[15]

1.2 Access and Benefit Sharing (ABS) systems

Over the last decades, regulations have been developed that aim to improve the sustainable use of GRs to protect biodiversity, and support benefit sharing. These regulations are also referred to as Access-Benefit Sharing (ABS) systems. The international treaty 'Convention on Biological Diversity' (CBD) of 1992 serves in many countries as starting point.[16] Since then, many countries and regions developed local ABS systems including laws, regulations, policies and administrative measures. However, these systems vary widely, although GR-rich countries tend to organize their systems more strictly and focus on acquiring an equitable share of the benefits.[17]

Exhibit 4 summarizes the actors in an ABS system: the GR providers (e.g. a local community in the Amazon), GR users (e.g. a university or a biotech firm) who develops new products based on GRs, and the end-users of GR-based products. . In between these actors are several government institutions involved in the process.

[15] See sources and data in Annex 6

[16] CBD 2010

[17] CISDL 2014

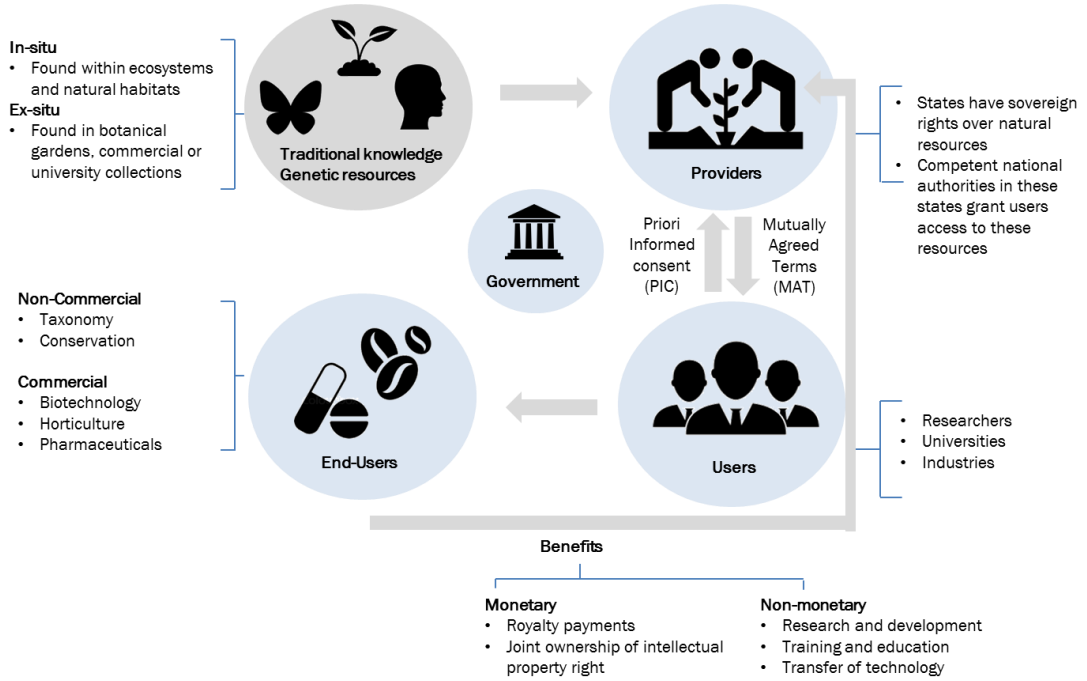

Exhibit 4: Summary of key actors and elements in ABS system

1.3 Disclosure requirements

Over the years, several governments introduced disclosure requirements (DRs) in the patent system as an extra component of ABS compliance. DRs relate to:

(i) The GR origin and/or source used in the invention;

(ii) Evidence of prior informed consent (PIC) on GR access;

(iii) Evidence of a benefit-sharing agreement (MAT).

Although it was discussed during the negotiations, the Nagoya protocol does not include a reference to DR as a checkpoint for ABS compliance.[18]

1.4 Research question and study scope

This research focuses on:

- What are the socio-economic effects of DRs?
- Is the DR procedure the optimal checkpoint to assure ABS compliance?

Chapter 2 introduces the study framework with references to other research, and chapter 3 and 4 describes the implications of DRs in the Brazilian and Indian case respectively.

2 STUDY FRAMEWORK

The research is based on literature review, a selection of interviews with ABS experts, and interviews with stakeholders in Brazil and India (local biotech firms, government bodies, IP law firms, academia).

[18] Nagoya Protocol 2014

The case studies have been selected based on number of GRs in country and presence of DRs:

- Brazil and India are rich in genetic resources (7.5% and 2.5% of global species, respectively);[19]
- Both countries implemented DRs more than 10 years ago.

Exhibit 5 provides an overview of the direct and indirect consequences of DRs on biotech firms (GR users), local communities (GR provider) and wider society (government, end-users). Theoretically, disclosure requirements are optimal when the societal benefits outweigh the costs. However, it also largely depends on how the costs and benefits are divided. Also, exact quantification of all effects is challenging (e.g. environmental effects, what is equitable?). Therefore, the results are presented as possible positive (+), negative (-) or uncertain (?).

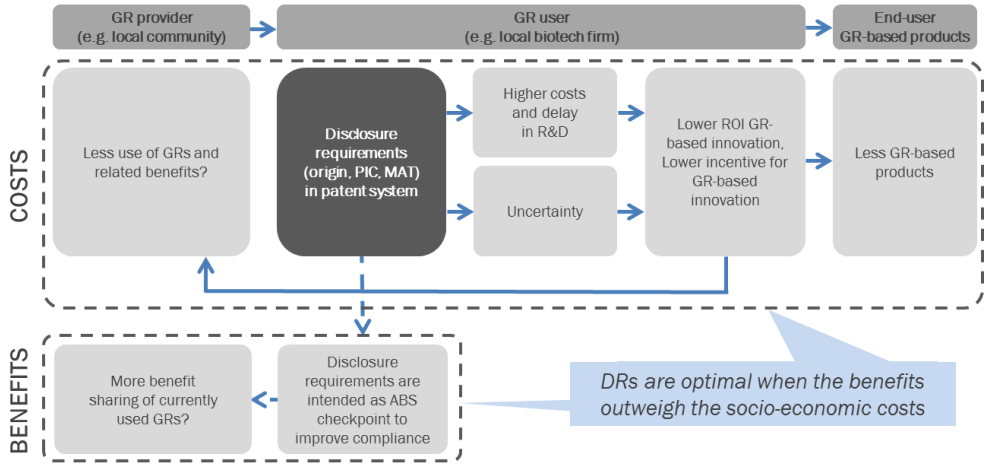

Exhibit 5: Costs and benefits in simplified GR value chain

In each case, we have asked the interviewees to compare a situation with DRs and without DRs (i.e. the counterfactual). This has been complemented by desk research on local trends of GRs use and historical ABS- and DR-related legislation.

3 General effects of Disclosure Requirements

ABS systems and the (historical) use of disclosure requirements in the patent system vary widely per country. However, we identified some general findings by analysing two specific cases (Brazil, India) and desk research of publicly available information.

Proponents of DRs allege that it stimulates ABS compliance and also stimulates GR use. This is based on the expectation that DRs will reduce granting erroneous patents over GRs and eventually increase benefits for local communities. Furthermore, supporters claim that securing ABS conditions in the patent system will increase transparency.[20]

On the other hand, opponents expect that the proposed benefits will not outweigh the societal losses. These could affect government (enforcement costs) and biotech firms (R&D costs, delay and uncertainty), which could eventually lower the levels of new GR-based products and thus lower benefits for local GR-communities and end-consumers. Sectors that are largely affected are the ones that make intensive use of both patents and GRs. These are for example the pharmaceutical sector and agriculture.

[19] UNEP 2004

[20] Henninger 2009; Saez 2016; ICC 2011; Oxley 2006; Nair 2010

The combination of patents and GRs implies a shortcoming of DRs as checkpoint, because many GR-based innovations do not involve a patent, e.g. FMCGs such as cosmetics. Therefore, DRs can only be a complete checkpoint in combination with other procedures. And, at the same time, many patented products do not reach the market. For these reasons, several interviewees involved in this research recommend an alternative checkpoint during the market authorization process of products.

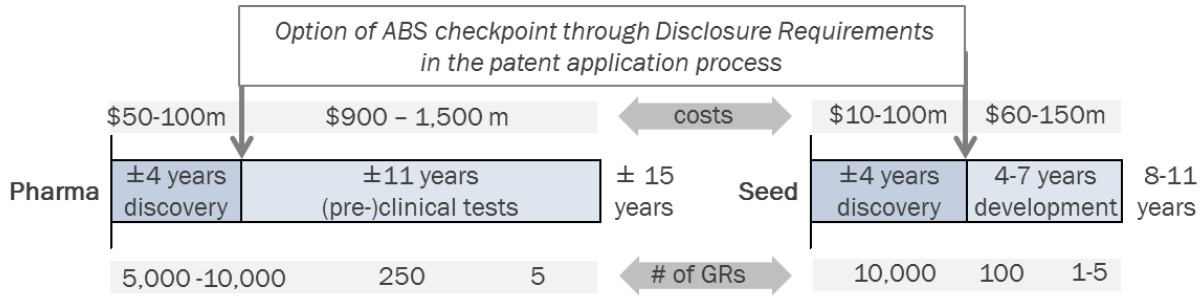

Exhibit 6: Examples of typical R&D cycles in pharma and seed sector[21]

DRs have a direct influence on the discovery phase of the R&D cycle. The length and costs vary widely per sector and innovation, but in seed and pharma it is on average 4 years with respective average costs of $12m and $60m. These cycles require on average ≥ 5,000 genetic materials to come up with a single innovation (Exhibit 6).

Public research and interviews with Brazilian and Indian stakeholders indicate that DRs might increase R&D costs, but the main burden is likely the delay and uncertainty. The uncertainty relates to unclear definitions of GRs (Brazil, India) and that DR content is not verified by the IP authorities (Brazil, India). This provides more room for challenging patents on ABS conditions after approval. The extent of the DR-effects on R&D cycles depends largely on local market conditions and (efficiency of) ABS legislation.

4 BRAZILIAN CASE

4.1 Introduction

Brazil is a country rich in natural resources, representing about 7.5% of global documented species (Exhibit 1). Exhibit 7 illustrates its biodiversity zones, of which 90% of its GRs relate to the Amazon. Whereas Brazil's biodiversity is unique, Brazil is also largely dependent on foreign genetic resources. For example, a large share of soybean and sugar cane the country produces for exports, finds it origin elsewhere. At the same time, innovation levels building on its GRs seem relatively low (e.g. low number of GR-based patents, see Exhibit 2).

In order to protect the country's GRs, Brazil took a first stance in the 1988 Brazilian Federal Constitution and later on implemented strict ABS legislation in 2001, complemented with the introduction of DRs in 2006. The DRs encompassed an authorization number provided by the Genetic Heritage Management Council (CGEN) that proves disclosure of GR origin and source, formal GR access (PIC) and the existence of a benefit-sharing agreement (MAT).[22]

In 2015, a new law was signed that aims to improve efficiency of the ABS system (including DR procedures), and is supported by the introduction of an electronic registration process for ABS conditions. Under the new system, the formal *authorization* from CGEN of disclosure of origin and source, and conditions for access permission (PIC) has been replaced by a formal electronic *registration and notification*, whereas the benefit-

[21] Adams et al 2006; DiMasi et al 2016; Phillips McDougall 2016

[22] Pinto 2016; Farani 2015

sharing agreement (MAT) is removed from the patent system and shifted to the market authorization process before final product commercialization.[23]

Exhibit 7: Brazilian biodiversity regions[24]

4.2 Scope

The key actors of the Brazilian ABS system are based on stakeholder interviews and desk research and are summarized in Table 1.

Table 1: Overview of key actors in Brazilian ABS system

Actor in ABS system	Brazilian organization
GR providers	Private landholders, local communities and gene banks
GR users	Direct users: Public institutions (e.g. Embrapa), local companies (e.g. Natura) Indirect: Other local and foreign companies
End consumers	Industry and consumers of GR-based products, within and outside Brazil
Government bodies	CGEN Genetic Heritage Management Council, independent authority under governance of Ministry of Environment, granting permits for GR use and enforcement INPI: National institute for intellectual property rights

For the analysis on the socio-economic effects of DRs in Brazil, the 'old' DR procedure (2006-2015) and new DR procedure (>2015) are compared to a situation without DRs (<2006). Exhibit 8 summarizes the study scope together with key contextual information on DR related legislation and GR access within Brazil. Between

[23] Kashiwabara 2017; Paes de Carvalho 2010; Union of Ethical Biotrade 2017

[24] Ministry of Environment (Brazil) 2014

2006-2015, disclosure requirements include evidence of source or origin, prior informed consent (PIC) and mutually agreed terms (MAT) with the owners of the genetic resources. After 2015, MAT is removed as a requirement and shifted to the final product development stage before commercialization.[25]

We note that the first ABS regulation, MP 2186-16 published in 2001, already included a DR obligation (source of origin, PIC, MAT).[26] However, the DR aspect related to the patent system was regulated in 2006 by a resolution published by CGEN, followed by another resolution published by the INPI. Until this point the applicants had no means to comply with the disclosure requirement regarding the IP system, nor had the INPI means to demand it from the applicants. Therefore, we focus on the time period 2006-2015 in this analysis.[27]

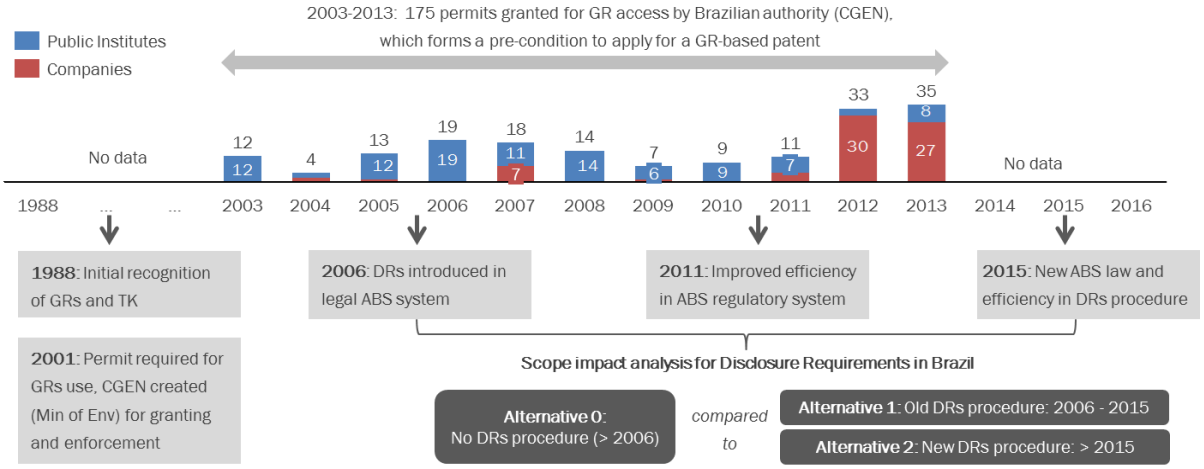

Exhibit 8: History of ABS regulation in Brazil and scope of analysis

4.3 Conclusions and recommendations

In the first 10 years (2006-2015), DR procedures delayed patent applications from months to over 2 years, increased third party costs for entities using GRs and uncertainty after patent grant (see Exhibit 9). The delay was mainly driven by the time to receive authorization from CGEN, which is required during GR-based patent applications, and the lack of knowledge of the proceedings (PIC, MAT) by communities and other actors involved. The uncertainty relates to both lack of clarity on scope and definitions (i.e. What should be disclosed?) and the fact that the IP body (INPI) does not verify the content of the DRs (i.e. it validates CGEN's authorization number). This implies that after patent grant, the patent could also be challenged on ABS conditions and could result in sanctions. However, other interviewees claim that this is optimal, as one organization remains the responsible and knowledgeable party in verifying and confirming correct genetic resources use.

From 2016 onwards, the new DR procedure tried to limit the burden by installing a new electronic process for acquiring formal GR access at CGEN (required for patent approval), as well as the removal of the benefit-sharing requirement (MAT) as a requirement. However, extra outsourcing costs for DR compliance and uncertainty after patent approval is likely to remain. Interviewees also expect that an efficient DR procedure might contribute to improved ABS compliance in the long run.

[25] Pinto 2016

[26] Interview INPI

[27] INPI 2017

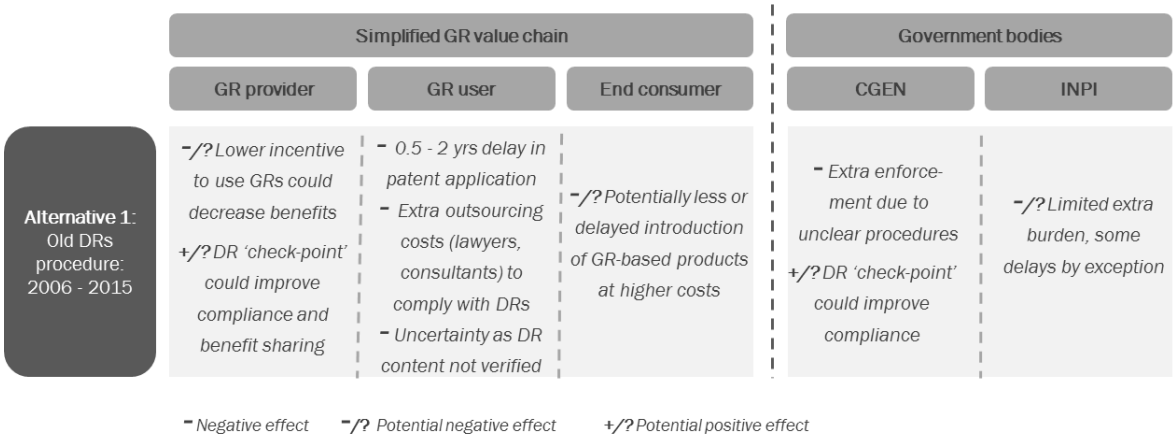

Exhibit 9: Effects of DRs during 2006-2015 (based on Brazilian stakeholders interviews)[28]

Interviewees indicated that using DRs as checkpoint captures only a part of GR-based innovations, while also many patented innovations will never reach the market. A checkpoint during the final phase of GR-based product development could be more effective given that this would (I) target both patented and not-patented innovations, and, (II) would focus only on GR-based products that are likely to reach the market. Within Brazil, this could be secured through the 'Notification of Finished Product' under the governance of the Ministry of Environment (MMA). The new law solves a part of this problem, as it moves at least the MAT requirement (i.e. proof of benefit-sharing) to the final development phase before market introduction.

5 INDIAN CASE

5.1 Introduction

India is a rich source of valuable GRs, with two of the world's 18 biodiversity hotspots: Western Ghats, and the Eastern Himalayas (see Exhibit 10). In total, it represents 2.6% of the global documented GR (see Exhibit 1).[29] These include high value plant species (7% of global), (which made India the country with the second-highest number of US Food and Drug Administration (FDA) approved plants).[30]

In 1994, India ratified the Convention on Biological Diversity, CBD. The Biological Diversity Act in 2002 (and Biological Diversity Rules in 2004) is meant to fulfil the objectives of the CBD, followed by the establishment of the National Biodiversity Authority (NBA) in 2003 to regulate GR related issues. In 2005, an amendment of the Indian Patent Act was introduced to make 'Disclosure of Origin and Source' for Indian GRs in patents compliant with the Biological Diversity Act (BDA).[31]

Recently, there have been some amendments to the ABS regulation. In 2014, the government issued new guidelines on access and benefit sharing, while since 2016 patent applicants receive an extra two months to comply with proof of ABS requirements.[32]

[28] CGEN 2016; Farani 2015

[29] UNEP 2004

[30] NAIR 2011

[31] Kohli 2015

[32] Khurani & Khurani 2017

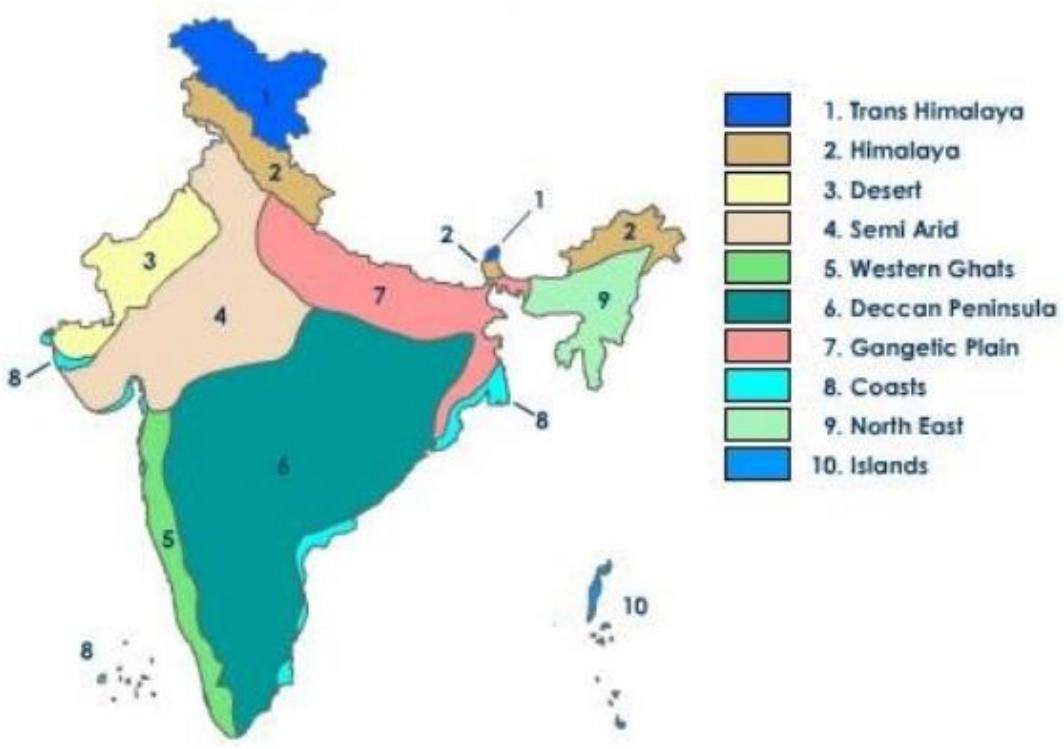

Exhibit 10: Biodiversity regions India

5.2 Scope

The key actors of the Indian ABS system are summarized in Table 2 and based on stakeholder interviews and desk research.

Table 2: Overview of key actors in Indian ABS system

Actor in ABS system	Indian organization
GR providers	Private landholders, local communities and gene banks
GR users	Direct users: Public institutions (Indian Agricultural Research Institute) and local companies (e.g. Biocon) Indirect: Other local and foreign companies
End consumers	Industry and consumers of GR-based products, within and outside India
Government bodies	Ministry of Environment, Forests and Climate Change NBA: National Biodiversity Authority, established by Central Government, performs facilitative, regulatory and advisory function on issues of the Indian ABS system State Biodiversity Boards, established by state governments Biodiversity Management Committees, established by local bodies Intellectual Property (IP) India for intellectual property rights, part of the Department of Industrial Policy and Promotion under the Ministry of Commerce and Industry

For the analysis on the socio-economic effects of DRs in India, we compare a situation before 2005 (without DRs) with a situation with DRs (after 2005). Exhibit 11 summarizes the study scope together with key contextual information on DR related legislation and GR access within India.

In this analysis, the scope is different from the Brazilian case. In the patent approval process, the Indian Patent Act of 1970 has always required disclosure of the source or origin of the biological material used in the invention. This procedure was independent of its origin (in or outside India). In the 2005 amendment of the Patent Act, patent applicants using GRs from India are obliged to comply with the 2002 Biological Diversity Act (BDA). This is a more strict procedure and is the focus of this analysis.

Note that the Indian regulations do not separately state refer to GRs, but predominantly refer to biological resources.

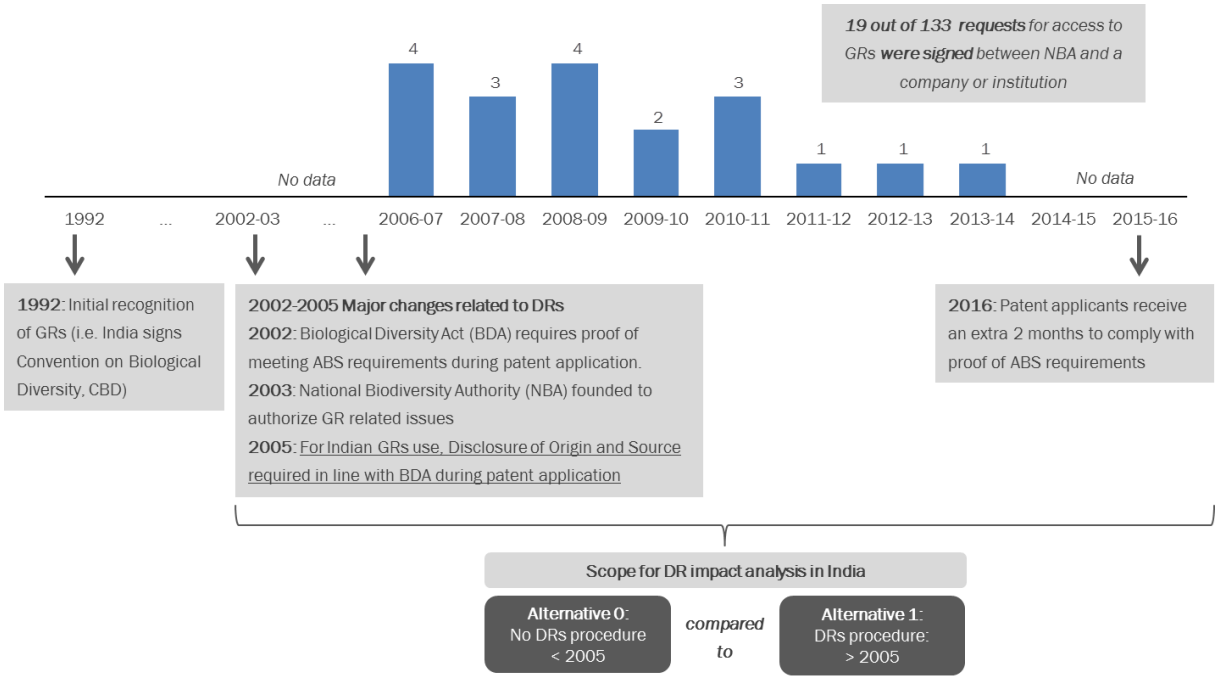

Exhibit 11: History of ABS regulation in India and scope of analysis[33]

5.3 Conclusions and Recommendations

In the interviews and review of public documents, several local and foreign stakeholders expressed their worries about the changes in the Indian system. Since the 2005 amendment of the Indian Patent Act (2005)[34], using Indian GRs in inventions became more difficult as it requires disclosure of origin or source that should be in compliance with the 2002 Biodiversity Diversity Act (BDA). This implies that applicants of biotech patents using Indian GRs need formal permission from the National Biodiversity Authority (NBA) before the granting process can proceed

IP lawyers who have been involved in these application processes indicated that obtaining permission from the NBA averaged four years in the initial years after 2005. Recently, the application process seemed to have improved and is estimated at 1 to 1.5 years. Note that the official term is 90 days. Statistics seem to underline the administrative challenges in access to GRs in India and patent applications based on Indian GRs. From

[33] Source: India Habitat Centre (2014); Remfry & Sagar (2015)

[34] The Patents Act, 1970 (as amended up to Patents (Amendment), Act, 2005), WIPO DR table April 2016

2006-2014, 19 of the 133 formal requests (14%) for Indian GR access were officially approved by the NBA, while only 63 of 574 applications (11%) received permission to apply for a GR-based patent.[35]

Also, interviewees stressed the complexity of having two separate bodies involved, while also the specific definitions seem inconsistent. For instance, de term 'biological material from India' in the Biological Diversity Act requires disclosure source of origin under a separate heading irrespective of where it comes from. On the other hand, the Patent Act requires disclosure only when biological material is insufficiently described or unavailable to the public.[36]

Disclosure Requirements only create a ABS checkpoint in the patent system, while interviewees indicated that many Indian GRs are commercialized without patents. Officially, non-patented products are covered in the BDA 2002 scope. But in reality this is largely up to the NBA and state biodiversity boards and consistent measures seem to lack.

Exhibit 12 provides a summary of the effects for the different stakeholders.

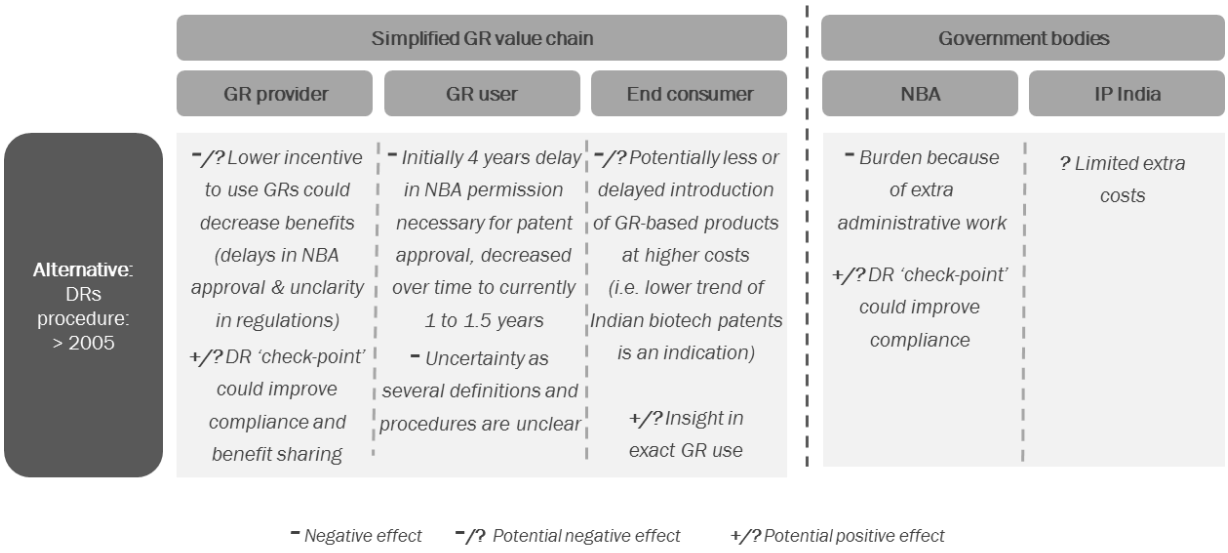

Exhibit 12: Effects of DRs after 2005 (based on Indian stakeholder interviews)

6 CONCLUSIONS AND RECOMMENDATIONS

This assessment provide insight in the challenges for patent applicants associated with disclosure requirements (DRs) for genetic resources. It is reasonable to expect that the unexplored GRs include a huge potential value, as less than 1% of species have provided the basic resources for the development of all civilization thus far. In both India and Brazil, DRs seem to have delayed the patent approval process, a phase where the chance of commercial success of a products is still highly uncertain. Furthermore, in India and Brazil regulations are perceived by several stakeholders as unclear or inconsistent. This creates additional uncertainty for patent applicants and thus also for providers and (eventual) users of genetic resources.

The results are built on a selection of stakeholder interviews and complemented with desk research. We believe that the framework presented in this report is supportive in the discussion on the effects of disclosure requirements and the ABS system in general.

[35] NBA 2015; Indian Habitat Center 2014; Indian Patent Office 2015; Remfry & SAgar 2015

[36] Prasad Oli 2009; Indian Habitat Center 2015; Sharma 2016; Remfry & Sagar 2015; Vadhera 2016

We note that the results could include an (unwanted) bias. Although we reached out to all relevant public stakeholders as we have not been able to interview all of the public stakeholders, e.g. the Brazilian biodiversity council (CGEN), India's National Biodiversity Council (NBA), representatives of GR-rich communities, and local NGOs in Brazil and India.

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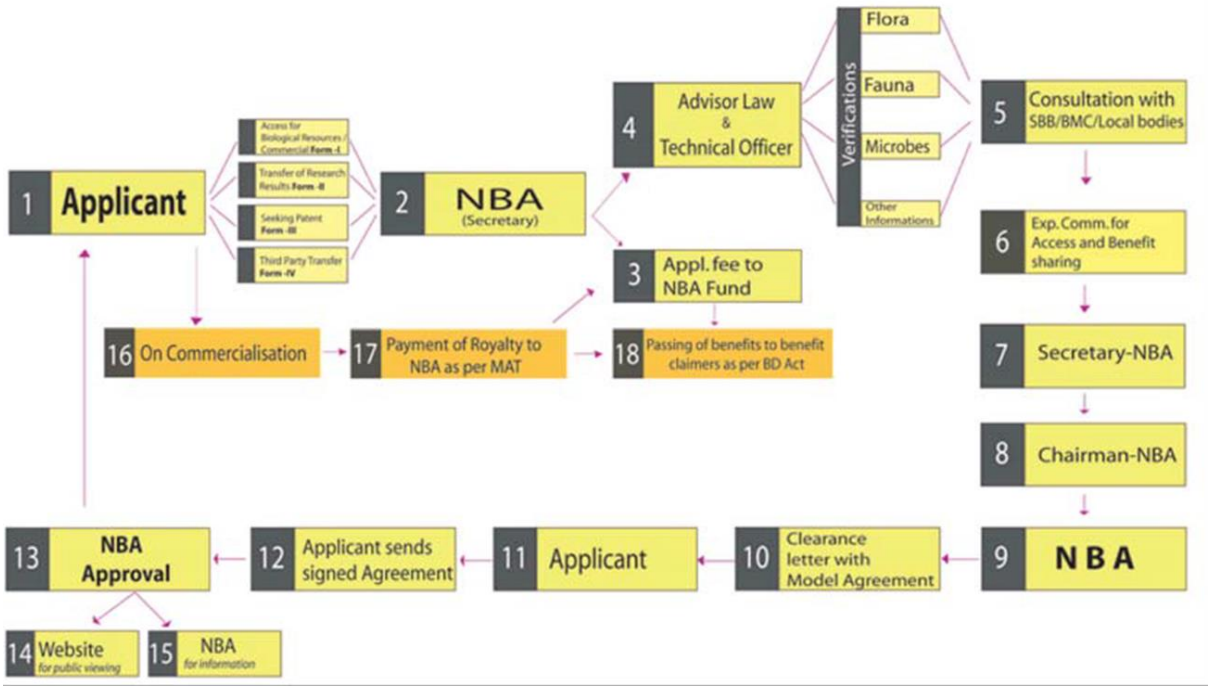
ANNEX 2: SUMMARY ABS LEGISLATION

Summary ABS legislation in Brazil

Year	Regulation	Content
1988	Brazilian Federal Constitution	Compels the federal government to preserve the diversity and integrity of the genetic heritage of Brazil and to control entities engaged in research and manipulation of such genetic material. Moreover, Section 4 of the same Article recognizes that areas deemed a national heritage, i.e., the Brazilian Amazon Rain Forest, the Atlantic Rain Forest, the Serra do Mar, the Pantanal Mato-Grossense, and the Coastal zones, shall be used only under conditions that ensure the preservation of their environments, including natural resources in such environments.
2001	Genetic Heritage Management Council (CGEN)	The foremost activities of CGEN are (i) to grant authorization for access to genetic heritage and shipment of samples of components of the genetic heritage and (ii) to grant access certificates to associated traditional knowledge. There are two pathways to obtain authorization from CGEN to access genetic resources in Brazil: (i) a non-commercial use pathway and (ii) a commercial-use pathway.
2003	Decree 4946/2003	More rules and regulations for companies seeking to obtain access to genetic heritage
2005	Decree 5459/2005	Provides for disciplinary sanctions for failing to abide by the regulations concerning access to genetic resources
2006	IP/C/W/474	Disclosure in the patent system
2007	Decree 6159/2007	"Contract for the Use of Genetic Heritage and Benefit Sharing" must be approved by CGEN prior to any technological development using the genetic resources and prior to the filing of any patent application. Moreover, this Decree places additional conditions and limitations regarding the use of genetic material.
2013	Resolution 69/2013	Requires applicants to inform INPI of the origin of the genetic material and of any associated traditional knowledge, as well as the Genetic Heritage Access Authorization number obtained from CGEN. If the patent application is not based on the use of any genetic material or traditional knowledge, a separate form must be submitted to INPI confirming this information.
2015	Law No. 13.123	The new law provides that researchers, R&D institutions and national companies can request the access to the biodiversity resources through an electronic registry in a database (yet to be created and regulated). Foreign companies can apply for access to genetic resources, provided they are associated with Brazilian R&D institutions. This measure replaces the previous authorization process to access genetic resources, which required the submission of documentation and reports to the Board of Management of Genetic Heritage (CGEN), which caused delays and high costs for applicants.

India, summary of process of gaining ABS approval under Biological Diversity Act for foreigners and non-resident Indians



ANNEX 3: OVERVIEW OF INTERVIEWEES

Brazil		
Contact	Organisation	Stakeholder group
Daniel Pinto	Intellectual Property Division - Brazilian Ministry of Foreign Relations	Government
Manuele da Silva	Fiocruz	Academic
Claudia Magioli	INPI	Industry
Adriana Diaferia	Grupo FarmaBrasil	Industry
Paulo Benevides	Centre for Biotechnology, former Natura	Industry
Gustavo de Freitas Morais	Danneman	Lawyer
Priscila Mayumi Kashiwabara	Kasznar Leonardos	Lawyer

India		
Contact	Organisation	Stakeholder group
Krishna Sarma	CLG India	Industry
Dr. Sharana Gouda	Ministry of Industrial Policy and Promotion	Government
Yogesh Gokhale	Teri Habitat Centre	Academic
Mr. Sharad Vadehra, Niharika Singh	Kan & Krishme	Lawyer
Debashish Banerjee	Remfry & Sagar	Lawyer
Gabriel de Blasi	Di Blasi, Parente & Associados	Lawyer

General experts		
Contact	Organisation	Stakeholder group
Paul Oldham	One Wold Analytics	Academic
Joyce Taite	University of Edinburgh	Academic
Maria Julia OLIVA	Ethical Biotrade	Industry/Academic
Kate Davis (referred to by David Castle)	University of Victoria	Academic

ANNEX 4: ORIGIN CROP SPECIES AS DOCUMENTED IN ITPGRFA

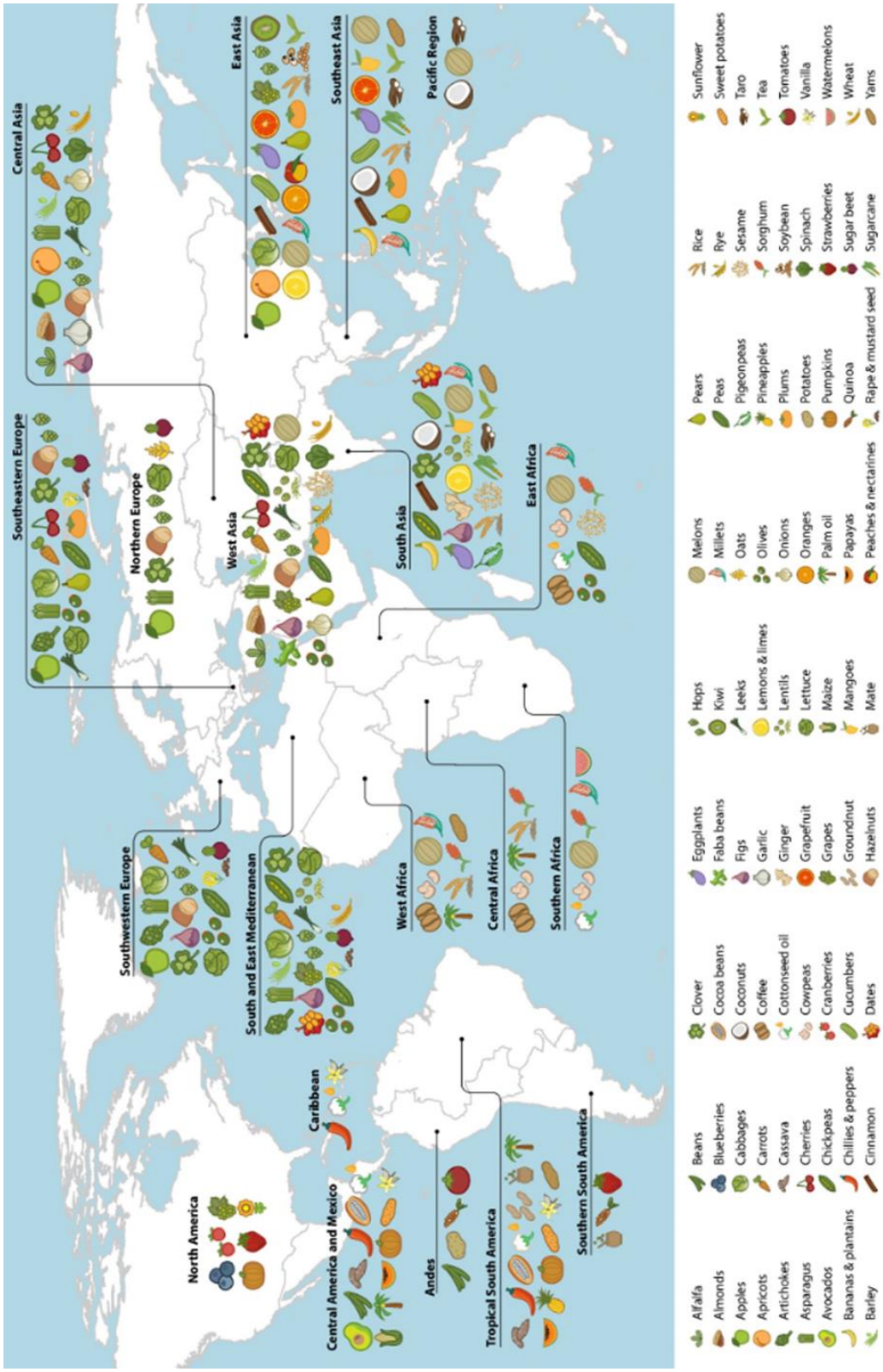


Exhibit 13: Origin crop species, IFPGRFA

ANNEX 6: TRADE BALANCE OF CROP AGRICULTURE

Brazil, 2014

Crop	Production (tonnes)	Export (tonnes)	Import (tonnes)	Production value (USD mln)	Export (USD mln)	Import (USD mln)	Crop information	Source
Soybeans	81,724,477	42,796,106	282,813	38,008	22,812	127	Round up ready + Genuity intacta RR 2 pro (gm based on glycine max, origin Asia);	AMIS Global Seed Database (2016); FAOstat (2016)
Cereals	100,901,726	28,674,738	9,660,049	22,941	11,842	1	Mixed, some might have origins in Brazil	FAOstat (2016)
Sugar cane	768,090,444	27,644,325	906	22,381	7,069	3,227	Hybrids of S. officinarum (original Asia, many hybrids Brazil), mostly CTC/RIDESA/IAC varieties	AMIS Global Seed Database (2016); Brasileiro et all (2014); FAOstat (2016)
Maize	80,273,172	26,624,890	911,387	16,217	6,307	159	Zea Mays varieties (origin Mexico), e.g. GM seed Yield Gard, hybrids origin in Brazil	AMIS Global Seed Database (2016); FAOstat (2016)
Wheat	5,738,473	1,188,299	7,273,279	1,461	348	2,414	Mainly based on Triticum Aestivium, Triticum durum and Triticum Spelta (European/Asian origin)	Wheat Atlas (2016); FAOstat (2016)
Cassave	21,484,218	48,838	107,033	2,890	11	12	Origin in Brazil	O'Hair et all. (1995); FAOstat (2016)
Oranges	17,549,536	23,208	14,598	2,163	10	12	No origin in Brazil	American Society for Horticultural Science (2011)
Bananas	6,892,622	97,976	4	1,538	35	0	No origin in Brazil	Heslop-Harrison, J.H. and Trude Schwarzacher (2007)
Tomatoes	5,738,473	1,492	542	1,439	1	13	Various varieties from Brazil	Morton (1997); FAOstat (2016)
Potatoes	4,187,646	2,023	29,180	1,378	1	1	No origin in Brazil (except for cassave)	World Potato Atlas (2006)

India, 2013

Crop	Production (tonnes)	Export (tonnes)	Import (tonnes)	Production value (USD mln)	Export (USD mln)	Import (USD mln)	Crop information	Source
Potatoes	4.534.360.000.000	165.855		3.845.380.209	34.490		Peru/Bolivia/Portugal	FAOstat
Cottonseed	1.229.310.000.000	1.888	66	2.292.136.799	604	7	India	FAOstat
Sugar cane	341.200.000.000	4.242	436	5.963.098.658	4.574	1.356	India	FAOstat
Vegetables, fresh	332.130.000.000	99.052	152	976.396.524	84.098	345		FAOstat
Bananas	275.750.000.000	37.150		6.351.123.689	26.495		India	FAOstat
Onions, dry	192.990.000.000	1.476.575		2.823.824.446			Iran/West Pakistan	FAOstat
Seed cotton	189.130.000.000			12.345.040.616			India	FAOstat
Tomatoes	182.270.000.000	228.444	4	4.428.860.851	69.721	3	Andes	FAOstat
Mangoes, mangosteens, guavas	180.020.000.000	263.918	653	10.662.985.142	204.310	737	India	FAOstat
Rice, paddy	159.200.000.000			6.108.399.482	8.205.309		China	FAOstat
Eggplants	134.440.000.000	126			84		India	FAOstat
Soybeans	119.480.000.000	5.193.476		3.762.649.328			China	FAOstat
Wheat	93.510.000.000	6.503.635		23.583.063.981	1.911.966		Levant region	FAOstat
Maize	23.290.000.000	4.749.727		4.420.216.667	1.264.042		Mexico	FAOstat
Coconuts	11.930.000.000	72.539		1.197.414.461	46.763		India	FAOstat
Millet	10.910.000.000	82.602		2.154.193.925	26.318		India	FAOstat