# Synthesis

# Economic potential and valorization opportunities for genetic resources in six African countries

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# **Executive Summary**

### **Overview**

The ABS Capacity Development Initiative has executed a regional UNEP/GEF project aimed at informing the development of national access and benefit sharing (ABS) frameworks in Cameroon, Kenya, Madagascar, Mozambique, Senegal and South Africa, with a particular focus on ways to bridge the gap between providers and potential user institutions; support the valorisation of genetic resources (GR); and increase the benefits arising from their utilisation.

The report "Economic potential and valorization opportunities of genetic resources under the Nagoya Protocol in Africa" synthesises the results of:

- Six studies on how the biodiversity of each country is reflected in the global patent system ("Patent studies")
- Six valorization potential assessments further exploring:
  - a) national actors related to the utilisation of GR
  - b) the links between patent documents, value chains and markets
  - c) country-specific interactions between national ABS frameworks and the valorisation of GR
- A sectoral analysis: R&D needs / requirements / opportunities for GR in four key industry sectors: Functional Food, Cosmetics, Pharmaceuticals, and Biotechnology.

Section 1 of this synthesis provides an overview of the current status of national ABS regulatory frameworks in the six countries.

Section 2 presents an overview of opportunities for countries to valorise their GR.

Section 3 presents a framework for pursuing valorisation opportunities.

Conclusions and recommendations aim to answer two main questions: How can a national ABS framework contribute to the valorisation of GR? What kind of business, legislative and regulatory environment is favourable for this purpose?

## **Key Findings**

Overall, there is a strong economic context for the valorisation of GR with an aggregated product market size of US \$1846 billion (2014 iii iii ii), with a predicted annual growth to 2020 ranging from 3.8 % in Pharmaceuticals to 12.3% in Biotechnology. Furthermore, across the four sectors examined, an aggregate of US \$124,4 billion was spent on R&D in 2013 by over 400 large companies. This figure excludes many more small and medium size companies with a strong focus on R&D<sup>v</sup>.

The potential economic gains that can be derived vary considerably from one R&D project to another. Microanalysis in functional foods and cosmetics suggests a minimum budget for a complete R&D project starts at €300 000. The budget for an initial screening of samples, where most provider institutions can participate, ranges from €5000 to €15 000. For ingredients successfully included in marketed products, the volume of raw material ranges from a few hundred kilograms to a few tons. More diversified benefits can be shared in the short, medium, and long term but they are not in the scope of this research. They are related to the provider institution level of investment in product and market R&D.

A framework is suggested for provider countries to concretise opportunities. First, an analysis of a country's biodiversity identified within the patent system can disclose species of economic interest. This project has undertaken the most detailed set of country-specific studies to date on patent activity involving GRand traditional knowledge (TK) across a range of markets. 221 species of potential economic interest were identified. Out of these, 33 species were examined for links to patent documents and value chains and markets. A positive link was identified in 40% of the cases. Refinement of this methodology could assist in future with further research of this type.

Secondly, the sectoral analysis of user institutions' R&D needs, requirements and opportunities related to GRshows that some have more interest in the scientific information accompanying a GR than in accessing a sample. Across all sectors, key opportunities exist for the valorisation of GR. There is increasing interest in using R&D partnerships to access and utilise GR. Furthermore, sector-specific opportunities have been identified. This is useful for provider institutions when positioning themselves to leverage additional value in the R&D process.

Thirdly, the countries' readiness to harness these valorisation opportunities shows that—in all countries examined—there is a core of credible R&D institutions. They constitute the basis for engaging in R&D partnerships. However, their support environment is often limited. Eventually, a range of solutions is suggested to overcome the evident lack of legal certainty, high transaction costs, and mistrust that are key barriers for reaching ABS agreements. Flexibility, ingenuity, and patience are required by all sides.

### Recommendations

In the context of ABS, R&D can be oriented to answer economic, social, and environmental challenges that are relevant nationally and abroad. The concrete spin-offs from access and utilisation should be anchored locally to provide a strong and stable base with which to secure international opportunities. Each country has been found to have a unique set of strengths to build on. In addition to country-specific recommendations made in the individual valorization potential assessments, two general recommendations are put forward for the valorisation of GR.

- 1. Continue to close the R&D gap by focusing on domestic strengths aligned with the relevant R&D needs of user institutions through:
  - Identifying the capacities and support needs of domestic R&D institutions
  - Clarifying market opportunities and the R&D requirements of user institutions
  - Targeting valorisation opportunities, leveraging strengths, and engaging in partnerships
- 2. Create an enabling environment that facilitates access for targeted user institutions / benefits by:
  - Establishing a supportive environment to leverage national R&D strengths
  - Drafting clear, and flexible ABS procedures to accommodate different types of user institutions
  - Targeting access and benefit sharing arrangements that allow domestic actors to move up the value chain
  - Valorising TKassociated to GR
  - Monitoring R&D practices.

Policy makers may wish to consider these recommendations when updating or developing national ABS frameworks to ensure such frameworks contribute to the valorisation of GRand any associatedTK.

# Introduction

The main objective of this report to inform the development of national ABS frameworks in Cameroon, Kenya, Madagascar, Mozambique, Senegal, and South Africa. For this purpose, it seeks to bridge the gap between providers and potential user institutions in order to support the valorisation of GRand associated TK with a view to increasing the potential benefits arising from their utilisation.

This synthesis ("Economic potential and valorization opportunities for genetic resources in six African countries") presents the results of the research carried out in:

- Six studieson the countries' biodiversity in the global patent systems ("Patent studies")
- Six valorization potential assessments further exploring:
  - a. The national actors related to the utilisation of GR,
  - b. The links between patent documents, values chains and markets, and
  - c. Country-specific recommendations to inform the development of national ABS frameworks and the valorisation of GR and TK
- A sectoral analysis "R&D needs / requirements / opportunities in four user sectors (Functional Food, Cosmetics, Pharmaceuticals, and Biotechnology)

The key findings of the report are presented in the following sections of this synthesis

Section 1 provides an overview of the current status of national ABS regulatory frameworks in the six countries.

Section 2 presents an overview of the range of opportunities for countries to valorise their GR. They are identified across the different components of this report.

Section 3 presents a framework to materialise these opportunities, including:

• The analysis of the countries' biodiversity as identified in the patent system as well as the links between patent documents, value chains, and markets:

A significant question addressed here regards the use of patent documents as an indicator of valorisation potential for the economic uses of African GR and TK.

• The patterns of R&D across the four sectors:

A range of questions are addressed to assist countries to support their provider institutions in valorising GR and in engaging in R&D partnerships with user institutions. This includes barriers in ABS agreements.

• The countries' readiness to harness the valorisation opportunities:

Institutions that are potentially using or involved in R&D on GR are identified. On this basis, potential strengths and weaknesses of a national framework for ABS and valorisation for GR are highlighted.

Finally, conclusions and recommendations are put forward to answer two main questions arising out of this research:

- How can national ABS frameworks contribute to the valorisation of GR?
- What kind of business, legislative, and regulatory environment is favourable for this purpose?

This report is based on a literature review, expert interviews, and internet research. Considering its wide scope from a geographical, economic, and regulatory perspective and the challenge of accessing relevant information remotely, the methodology used evolved as information and key findings became available. The report does not purport to be exhaustive. It is envisaged that this preliminary analysis will contribute to identifying issues requiring further in-depth research and analytical work.

# 1. National legal and regulatory frameworks that contribute to an enabling environment for the valorisation of genetic resources

Among the countries covered by the study, Kenya, Mozambique, and South Africa adopted national ABS measures in accordance with the *Convention on Biological Diversity's* (CBD) access and benefit-sharing (ABS) provisions, prior to the adoption of the *Nagoya Protocol on Access to Genetic Resources* and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Nagoya Protocol) in October 2010. Following ratification of the Protocol, these countries are in the process of revising their national ABS frameworks to take into account the obligations of the Nagoya Protocol.

Madagascar has ratified the Nagoya Protocol and Cameroon has completed its national ratification process; however, its official ratification is pending deposit of the instrument of ratification. Both countries are in the process of developing national ABS measures, taking into account the provisions of the Nagoya Protocol. Finally, Senegal has not yet ratified the Nagoya Protocol and is currently working on the development of a national ABS strategy.

# 2. Opportunities to valorise genetic resources

There is a strong economic basis to capture opportunities to valorise GR across the four sectors. This is demonstrated by market size and its dynamic growth. The aggregated market size of the four sectors is US \$1,846 billion for the four sectors in 2014. Annual growth to 2020 is forecast to range from 3.8% in Pharmaceuticals to 12.3% in Biotechnology. R&D expenses also follow a growth trend with an aggregate of US \$1,244 spent by over 400 large companies across the four sectors. Their R&D budget is growing as the following shows:

- Functional foods: \$8 billion of R&D investment, 2.7% annual growth (2010 / 2013)
- Cosmetics: \$3 billion of R&D investment, 6.7% annual growth (2010 / 2013)
- Pharmaceuticals: \$ 96 billion of R&D investment, 3.1 % annual growth (2010 / 2013)
- Biotechnology: \$ 16.7 billion of R&D investment (annual growth figure not available).

This R&D investment led to 87,169 patent grants in 2013.<sup>6</sup> The number of patents is also on the rise. Moreover, there is a higher success rate for patent applications. The patent propensity (fewer patent applications, more patent grants) is also increasing. While all regions are on the rise for patent grants, Africa has the lowest figures and its rate of grants is decreasing.

<sup>&</sup>lt;sup>1</sup> Functional Food and Nutraceuticals Market (2014 - 2020), Research & Markets, 2014.

<sup>&</sup>lt;sup>2</sup> Global Cosmetics Market. Research & Markets. 2015.

<sup>&</sup>lt;sup>3</sup> Total non-audited and audited Global pharmaceutical markets by region 2014 - 2019, IMSHealth, 2014.

<sup>&</sup>lt;sup>4</sup> Biotechnology Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2010 – 2017, Research & Markets, 2013.

<sup>&</sup>lt;sup>5</sup> EU Industrial R&D Investment Scoreboard, world's top 2.500 R&D investing companies. 2014

<sup>&</sup>lt;sup>6</sup> WIPO patents statistics database spring 2014

This compares with a level of aggregated R&D expenses<sup>7</sup> of US \$3.2 billion across the six countries in 2010. On average, this represents 0.52% of national GDP.8

The potential gains and benefits that can be derived by provider countries and their R&D institutions varies from one R&D project to another as there is no standard model. However, microanalysis in the functional food and cosmetics sectors suggests budgets per R&D project start at a minimum of €300,000. The budget for a very initial screening phase, where most provider institutions could participate, ranges from €5000 to €15 000.

In practice, companies in these two sectors have, on average, a 10% success rate for their R&D projects (i.e., a product or service launched on the market). R&D processes are therefore complex, expensive, and risky. There are no rules of success for an R&D project. While an average minimum budget for a completed R&D project is €300 000 many projects are stopped well beforehand. For instance, the budget for an initial screening to identify potential leads—where most potential candidates fail ranges from €5 000 to €15 000. In the meantime, the cost of regulation, including new ingredient registration, is rising in all regions.

In this context, it is difficult to evaluate the Return On Investment (ROI) in R&D. For new product ingredients successfully marketed, the volumes of raw material necessary for commercial production generally vary from a few hundred kilograms to a few tons.

Studies undertaken in this project enabled the identification of economic opportunities and clear pathways for the valorisation of GR. The studies identified, the countries' biodiversity as referenced in patent documents, the links between patent documents, value chains, and markets; the research landscape of R&D actors and the sectors' R&D trends.

An opportunity is identified when a connection is possible between a domestic R&D actor or a species under research and a user institution's R&D needs. Hence, the availability of information is essential for opportunity identification. Three main sources of opportunities were identified:

- Species and actors related to R&D in the provider countries
- Species and technology areas in the patent documents
- R&D needs in dynamic market segments.

For instance, Kenya has a national vision for its development (Kenya 2030). One development component for agriculture is to reduce fertilizer costs by improving the purchasing, supply chains and supporting local manufacture of fertilizer. In this context, an opportunity could be explored between the Jomo Kenyatta University of Agriculture and Technology that has a research project on organic farming and the patent assignee that developed an organic insecticide from the Kenyan species of Chrysanthemum cineraria folium.

<sup>&</sup>lt;sup>7</sup>Expenditures for research and development are current and capital expenditures (both public and private) on creative work undertaken systematically to increase knowledge, including knowledge of humanity, culture, and society, and the use of knowledge for new applications. World Bank, 2016.

<sup>&</sup>lt;sup>8</sup> R&D expenses, World Bank, 2016.

<sup>&</sup>lt;sup>9</sup> http://www.vision2030.go.ke/index.php/pillars/project/Economic/33 (accessed 3 March 2016)

# 2.1 Valorisation opportunities identified across the four sectors

### **Common Opportunities**

# Systematic sampling

Actors, such as botanical gardens, that are able to carry systematic sampling<sup>10</sup> with correct taxonomic information<sup>11</sup> can respond or proactively meet user institutions' demand for particular types of species or genes as they target specific activities.<sup>12</sup>

### **Exotic genetic resources and African plants**

There is an interest in exotic GR, when they can procure a form of exclusivity<sup>13</sup>, and in African plants, due to the continent's high biodiversity. However, Asia and Latin America are growth markets and they also have high biodiversity<sup>14</sup>, which has logistical and regulatory advantages for bioprospecting.

# Associated traditional knowledge (TK)

New models for the sustainable commercialisation of indigenous natural plant ingredients based on associated TK are emerging. The objective here is to use associated TK as a proxy indicator for safety and efficacy when targeting innovative ingredients. A particular feature of this model is that it occurs in a pre-R&D phase before the commencement of corporate R&D.<sup>15</sup>

### Scientific partnerships

Companies are open to scientific partnerships as they become more interested in the scientific information accompanying the GR than in the sample itself.<sup>16</sup>

# **Sector Specific Opportunities**

In functional foods and cosmetics, there is a common opportunity for **niche ingredients that provide** a **unique, green, and/or ethical story.**<sup>17</sup> There is a growing market for niche items as they continue to emerge and be provided to consumers as unique products, particularly in the context of high-end market products. Suppliers will find greater reward in the market for more exotic flavours, such as the ones made from raw materials collected in the wild or those of unique origin. The story behind the ingredient and the implementation of sustainability principles are key too.

A range of opportunities specific to each sector is identified in Table 1, which follows.

<sup>&</sup>lt;sup>10</sup> B. Barnes, Director IP & Global Health, European Federation of Pharmaceutical Industries and Associations, 2014. Pers. Comm.

 $<sup>^{\</sup>rm 11}$  B. David, Institut de Recherche Pierre FABRE, 2015. Pers. Comm.

<sup>&</sup>lt;sup>12</sup> Global biobanking conference, 2016

<sup>&</sup>lt;sup>13</sup> M. Rots, Deputy Head of Patent Group, VP Patents - Food & Refreshment, Unilever Patent Group, 2015. Pers. Comm.

<sup>&</sup>lt;sup>14</sup> X. Brochet, Director of natural innovation, Firmenich, 2015. Pers. Comm.

<sup>&</sup>lt;sup>15</sup> C. Lombard, CEO Phytotrade. 2014. Pers. Comm.

<sup>&</sup>lt;sup>16</sup> Interviews with R&D experts: A. Billy, Director R&D, Naturex. P. André, Director Cosm'ethic (former Director of Botanical Innovation, LVMH). F. Gattesco, Senior R&D scientist, Indena. C. Lombard, CEO, Phytotrade Africa. O. Lafond, Expert in agro-industry strategy, Consultant. . X. Brochet, Director of Natural Innovation, Firmenich. C. Ambroset, ingénieure de recherche en biologie Anses laboratoires de Lyon. 2013 – 2016; Pers. Comm

<sup>&</sup>lt;sup>17</sup> CBI, Centre for the promotion of imports from developing countries. Market information reports on a) Cosmetic ingredients and b) Natural colours, flavours and thickeners. 2015 <a href="https://www.cbi.eu/market-information/">https://www.cbi.eu/market-information/</a> (accessed 14 July 2014)

	Functional food	Cosmetic	Pharmaceutical	Biotechnology		
Size of the opportunity	bn by 2020 with a higher growth - Approximately 1/3 of R&D project	ients: from US \$9.29 bn (2014) to US \$14.25	<ul> <li>23.8 % of the R&amp;D budget (US \$32.6 bn in 2012) is allocated to the pre human / pre-clinical phase<sup>xiv</sup>; where GR can be of potential interest.</li> <li>Natural derivatives are only one avenue for discovering new leads<sup>xv</sup></li> <li>High numbers of new R&amp;D projects<sup>xvi</sup> but only a very few new actives obtain a market authorisation<sup>xvii</sup></li> <li>Emerging markets are becoming growth markets with specific needs</li> </ul>	- The market for segments, including bioagriculture, bioservice, and bioindustrial, represents approximately US \$129.6 bn in 2013 (outside pharmaceutical biotechnology that represents 60 % of the sector). The R&D intensity is high (35%) and increasing xviii.		
Type or area of the opportunity	- Consumer demand for:	nt, healthy products and ethical sourcing th, well-being. The well-being. The well-being products for targeted customer segments include to target segments to target specific segments.  - Nutricosmetic - New colour palettes - Treatments to target specific skin types and conditions - Multifunctional formulas answering different needs - Male cosmetics.  Embryonic move towards a 100% vegetal industry, using only natural ingredients to target specific skin types and conditions to target specific skin types and conditions.	<ul> <li>Focus on lead discovery as methods for selection of potential leads are less developed**xxvi.</li> <li>Explore natural health trend demand**xxviii</li> <li>Establish R&amp;D partnerships: user institutions are looking for breakthrough innovation typically derived from biotechnology and academia and for collaborations to facilitate market understanding and to further explore related innovation hits**xxviii</li> <li>Research areas focus on improving the targeting of healthcare for a wide range of diseases**xxix xxxx xxxxi</li> </ul>	<ul> <li>Connect academic research findings with sectors' R&amp;D needs, such as the valorisation of biomass<sup>xxxxii</sup>, carbon sequestration<sup>xxxiii</sup> (the bulk of the sequestration can be undertaken by microbiological action).</li> <li>Create start-ups on the model of pharmaceutical biotechnology industry for cosmetics and functional food with innovative ingredients from academic laboratories<sup>xxxiv</sup></li> <li>Research areas focus on issues related to<sup>xxxv</sup>:         <ul> <li>Energy scarcity</li> <li>Demand for cleaner and more efficient industry</li> <li>Finite resources that are missing (including raw materials, water and fertile soil).</li> </ul> </li> </ul>		

# 2.2 Valorisation opportunities identified in patent documents

#### Overview

This section presents an overview of the findings of the six country studies covering "Biodiversity in the Patent System". The main question addressed in these studies is what patent information can teach us about the range of potential economic uses of African (GR) and TK.

The outcomes of this work are the most detailed set of country studies to date on patent activity involving GRand TK from specific countries across a range of markets. The author of this work published a related scientific article: *Biological Diversity in the Patent System* (Oldham et al., 2013)<sup>18</sup>.

With regard to the species and the patent documents in the scope of this research, 116,950 species were identified as an aggregate of the species occurring in each of the six countries through the Global Biodiversity Information Facility (GBIF). Then, 975,419 patent documents containing species known to be distributed in each country were identified in the global patent system. Of these, 3,602 made direct or some form of reference to the country studied. Of these, 221 species were identified as presenting a potential economic interest. Out of these, 33 species were selected to link the related patent documents with value chains and markets.

#### Country specific opportunities

Opportunities were identified in patent documents for species and related technology areas. As the analysis was focused on each country, the example of Madagascar is presented to highlight the type of opportunities identified. The analysis focused on species that are known to be distributed in Madagascar and elsewhere and species that were directly sourced from, or potentially originate from, Madagascar based on distribution data.

The Global Biodiversity Information Facility<sup>19</sup> indicates 23,220 records of species for Madagascar. In total, 6,764 species names that are known to occur in Madagascar were identified in the patent data from major jurisdictions. The patent activity typically involves research and development that targets particular organisms (i.e., pathogens), important agricultural crops or plants that are a source of approved pharmaceutical drugs or other medicines.<sup>20</sup>

In total, 73 species were identified as directly sourced from or potentially originating from Madagascar. (Among these, four were examined to identify links between the patent documents with associated value chains or markets.) The main technology areas are pharmaceuticals, biotechnology, and peptides. Some species are the focus of activity for a range of different products, technology, and markets (Graphic 1).

The top three claims in the patent documents refer to methods of producing a plant, processes for producing a desired product, or composition (e.g., extracts, compounds, or combination of

<sup>&</sup>lt;sup>18</sup> http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0078737 (accessed 29 February 2016)

<sup>&</sup>lt;sup>19</sup> The Global Biodiversity Information Facility (GBIF) is an international open data infrastructure, funded by governments. It allows anyone to access data about all types of life on Earth, shared across national boundaries via the Internet.

 $<sup>^{20}</sup>$  Oldham P, et al. 2013. Biodiversity in the global patent system: Madagascar.

ingredients) (Graphic 2). However, the interpretation of patent claims requires careful attention to both the type and framing of patent claims as well as where and whether the patent is in force.

The analysis based on patent citations, revealed three species (*Euphorbia hedyotoides, Ravensara anisata* and *Cedrelopsis grevei*) with potential for economic development related to the patented inventions. The analysis of the patent family identified two species of importance to the applicants (*Adandosia digitata* and *Theonella swinhoei*), where further R&D partnerships could be explored.

Adansonia digitata	Cosmetics	2			
	Hyperglycaemia/Diabetes	2			
	Skin Care	2			
	Traditional Medicines	2			
Adansonia fony	Cosmetics	4			
	Hyperglycaemia/Diabetes	4			
	Skin Care	4			
	Traditional Medicines	4			
Adansonia grandidieri	Animal Feed	3			
	Animal Food Supplements	2			
	Cosmetics	8			
	Hyperglycaemia/Diabetes	5			
	Skin Care	6			
	Skin Disorders	1			
	Sun Barriers/Sun Tan Lotion	2			
	Traditional Medicines	6			
	Vitamins	2			
Adenoplusia axillaris	Cosmetics	2			
	Skin Disorders	1			
	Traditional Medicines	2			
Aloe bakeri	Biotechnology/Genetic Engineering	2			
	Flowering Plants	2			
Bryophyllum beauverdii	Biotechnology/Genetic Engineering	4			
	Flowering Plants	4			
	Undifferentiated Cells From Plants				
Catharanthus longifolius	Biotechnology/Genetic Engineering	6			
	Flowering Plants	6			
	Flowers	3			
	Peptides From Plants	6			
	Recombinant Dna Technology, Plants	3			
	Stem Cells/Plant Meristems	3			
Catharanthus ovalis	Biotechnology/Genetic Engineering	6			

Graphic 1: Species and technology areas

Source: Oldham P, et al. 2013. Biodiversity in the global patent system: Madagascar

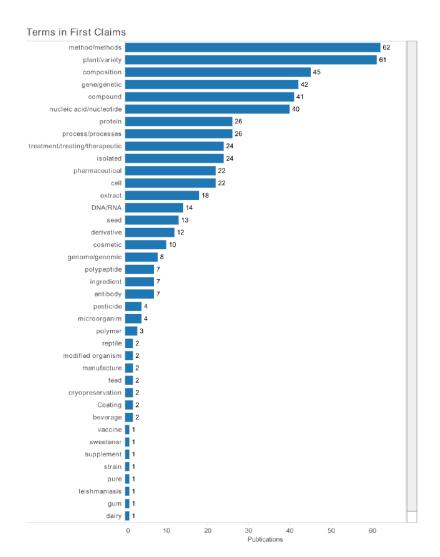


Table 4: Terms Appearing in the First Claim of Patent Documents

Graphic 2: Claims appearing in the first claim of patent documents

Source: Oldham P, et al. 2013. Biodiversity in the global patent system: Madagascar

# 2.3 Valorisation opportunities identified in linking patent documents with markets

# Overview

This section presents an overview of some patent documents examined for the six countries in order to identify links with value chains and markets. Patent documents are a pertinent source of information to identify opportunities within value chains and markets and as an indicator of R&D. As such, they can constitute a trigger for further examination of economic potential. However, there are some methodological limitations for the scaling up of this approach.

In total, 58 of the 211 species with an economic potential were selected for further analysis. Out of 1,478 patent documents, 113 were specifically examined.<sup>21</sup> An overview of the results regarding the links identified between patent documents with value chains and markets is presented in Table 2 below.

These species are mostly *plantae* but there are also bacteria, micro-organisms, *fungi* and *animalia*. The majority of the patent documents are for the pharmaceutical sector, followed by cosmetics. Overall the majority of documents were for the business-to-consumer (b2c) segment (e.g., ornamental horticulture), and few in the business-to-business (b2b) segment (e.g., a de-pollution technology). The information available in the patent documents examined did not reveal the potential provider in the countries or evidence that ABS requirements were taken into account.

On average, 40% of the patent documents examined could be linked to a concrete value chain and market. For 44% of the patent documents examined, no link could be identified; while the remaining 16% the linkages were unclear, due to insufficient information.

Overall, the mention of TKwas identified in 53% of the patent documents examined. However, the study does not examine whether TKis related to the invention. In the majority of the cases, it is included in the patent document as background information. Therefore, considerable care is needed in interpreting whether TK forms part of the invention. Unsurprisingly, it is generally identified for the innovation related to *plantae* and a lot less for those related to *animalia*, *fungi*, and bacteria.

These are preliminary findings, since at present there is no baseline data to provide accurate quantitative measures on how to interpret these figures. In other words, there is no well-defined scientific methodology for identifying what these statistics really mean. Refinement of this methodology could assist in future with further research of this type.

The methodological approach undertaken was to select a range of species that presented potential economic interest as they directly relate to the individual country biodiversity as identified in the reports on the countries' biodiversity in the global patent system (section 2.2.). A focus was placed on patent documents making direct reference to species that were directly sourced from, or potentially originate from, the countries studied and based on known distribution data. The species selection was based on ones most referred to in patent documents, or that had high numbers of patent citations<sup>22</sup> or large patent families.<sup>23</sup> When there were too many patent documents to examine for a given species, either a focus was given to those held by the patent assignees that hold the majority of them or in some complex cases, a random selection was realized.

<sup>23</sup> A patent family is the total number of patent documents, related to the same invention, that are submitted by a single assignee, for protection of the invention, in different geographical areas. It is an indicator of the importance of the invention to the assignee. It is a demand for protection represented by its willingness to pay a fee for maintaining patent documents in different geographical jurisdictions.

<sup>&</sup>lt;sup>21</sup> Two reasons explain the difference between the number of species and the number of patent documents. First, different organisations can hold a patent on a same species of microorganisms or part of a species. Secondly, an inventor generally seeks to protect his or her innovation at different points in time as R&D progresses and also diversifies.

<sup>&</sup>lt;sup>22</sup> A citation occurs when a patent document is cited or mentioned in another patent document. It is a measure of the importance and impact of the quoted patent document within the patent system.

		Cameroon	Kenya	Madagascar	Mozambique	Senegal	South Africa	Total	Total %	
	Species identified with economic potential	22	29	73	10	18	110	211		
Species	Species selected for the researching links with value chains and markets	8	9	4	10	6	5	33	16%	
	Total number of patent documents for the species selected for further analysis.		49	67	27	1035	75	1473		
	Patent documents examined:									
Patent	Links with a value									
documen	chain or market:									
ts	Yes, link identified.	4	3	1	23	2	20	53	40%	
	Unclear	0	3	8	3	7	0	21	16%	
	No link.	5	28	5	2	3	14	57	44%	
	Total	9	34	14	28	12	34	131	100%	
	Mention of traditional knowledge	9	16	8	13	6	17	69	53%	

Table 2. Overview of the patent document examined to link with value chains and markets

Country-specific opportunities: Wider industrial and scientific information related to the patent document(s)

Based on the Internet research conducted, some species were identified as being subject to on-going research beyond the purpose of the patent document claim. Hence, they may have economic potential in other value chains and markets. As the analysis was focused on each country, the example of Kenya is presented to highlight the type of opportunities identified.

In summary, five out of the nine species examined are subject to on-going research, especially in the pharmaceutical and biotechnological sectors (annex 1). No particular additional conclusions can be drawn from this information with regard to the valorisation of GR, as it is unclear at this stage if these products or R&D are based on the GR. There is, however, a clear indication of the economic potential of the species. Hence, these cases are of potential interest for further exploration.

# 2.4 Valorisation opportunities identified in the analysis of R&D actors

For Cameroon, Madagascar, Mozambique, and Senegal, opportunities are mostly related to the presence of provider institutions with credible scientific and/or R&D experience. In South Africa and Kenya, more concrete opportunities could be identified, as there is detailed information on research activities and programs, the species studied, and the national policy objectives for development, R&D, and innovation. The level of precision for opportunities identified at the country level depends on the level of information publicly available. All opportunities would require further exploration in order to be confirmed. A summary of opportunities is listed below.

### • Cameroon

- Network of R&D actors at the regional level in the Congo Basin
- Diversity of domestic actors related to R&D in a broad range of areas, including a leading scientific institution on plant chemistry
- A few companies and NGOs sensitised to ABS

### Kenya

- Large support environment including a national bioprospecting strategy and a business incubation association
- Diverse public institutions providing access and doing R&D on GR
- Gene databases (i.e., plant, tree, animal) housed in institutions with a mandate to promote their exchange
- Research programmes in universities covering a wide spectrum of species for various industrial and market applications

# Madagascar

- An expertise on international large scale bioprospecting with domestic public institutions capable to undertake initial phases of R&D (e.g., taxonomy, sampling, basic screening of activity)
- Limited information found on universities, but there is a recent best practice guide on ABS for non-commercial research
- Few, but experienced domestic companies and NGOs valorising GR

### Mozambique

- A national strategy on biotechnology since 2009 and a few public institutions, some newly created, doing research on marine resources for biotechnology purposes

### Senegal

- Some research taking place in the universities and in public institutions, but their specific fields of activities are unclear
- A leading scientific actor carries out ethno-botanic research and houses a major regional botanical garden
- Production and export of two major commodities where there is on-going R&D at the international level

# South Africa

- Many public and private organisations doing research across a large cross-section of areas with R&D champions having high level expertise in specific fields
- Consortium of actors with capacity to cover almost the whole R&D process, from sampling to setting up a value chain
- R&D partnerships through research councils and a wide range of initiatives and fora. There are many R&D collaborations with foreign actors.

# 3. A framework to solidify valorisation opportunities

To unlock potential valorisation opportunities for GR, countries and their R&D actors can consider a range of elements to inform decision making, including:

- The status of their biodiversity identified in the patent system and links to markets
- The market opportunities and the related user institutions' R&D needs and requirements
- The readiness of the R&D institutions to create and grasp opportunities
- The challenges for implementing PIC and MAT to facilitate the valorisation of GR.

# 3.1 Countries' biodiversity in the global patent system and links to markets: Species of economic interest but unclear paths to markets

The research on a country's biodiversity in the patent system identified a number of species with potential economic interest. This is based on two indicators: the size of the patent family and the number of first filings.<sup>24</sup> In both cases, it is key to understand that a patent may or may not relate to a specific product or service. While in legal terms a patent document equals to an invention, in economic terms there is no straight relation between a patent document and its commercial use in a market. Furthermore, one product or service may contain multiple patent documents for a range of compounds, extracts, and the properties of its ingredients.

Patent documents are a useful tool for improving the understanding of valorisation challenges and opportunities for GR. They constitute a proxy indicator of market interest, but not necessarily of value. The analysis of patent documents to identify links with value chains or markets contributes to a better understanding of user institutions' R&D practices and of species' valorisation potential.

The identification of linkages provides a point of entry to identify key elements of relevance to the valorisation of GR. They include, for instance, information on the market potential of a species, the R&D process, and the related actors that led to the invention. This can assist in determining the potential for a domestic R&D actor to integrate a particular R&D process and/or further support R&D on a species. However, this type of analysis mostly provides a historical perspective. Considering the rapid change in science and technology, additional information is necessary on future trends (section 3.2).

However, it is also important to emphasise the insights gained in the course of this pilot research project including the limitations of the research.

The present research is limited to the collections of the European Patent Office, the United States Patent and Trademark Office and the Patent Cooperation Treaty. The research did not examine filings of patent applications purely in national offices except in cases where additional research was

<sup>&</sup>lt;sup>24</sup>A first filing is the legal term used to qualify the first patent document that is submitted by an assignee in a jurisdiction. There can be many first filings for a same species, by one or more assignees. This is an indicator of inventiveness on the species. This means that species have different careers across different sectors and market; a sort of social life. The more first filings an assignee has on a species, the more important the species is to him.

conducted to expand coverage. As such, the research results focus on international patent activity at the major patent offices.

Monitoring patent activity for GRand TK is increasingly possible using cost-effective computational approaches. However, monitoring capacity is fundamentally dependent on the availability and quality of taxonomic information and geo-referenced records. We therefore advocate increasing attention to basic taxonomic research and to increased coordination between national collections and the Global Biodiversity Information Facility (GBIF) to improve country-level coverage and access to basic taxonomic information.

Species that appear in patents typically occur in more than one country. In the absence of more complete taxonomic information, it can be difficult to determine with accuracy whether a species is truly endemic (unique) to a particular country. We use the terms endemic, uncertain, and cosmopolitan in the country reports with the caveat that the determination of endemism requires consultation with taxonomic specialists.

A single species may be used at different research levels (e.g., raw extracts, compounds, or DNA sequences) in potential products directed to a range of markets. It should not be assumed that species are only relevant to one market.

Species may appear in a patent document for a variety of reasons. A species may be the source of an invention (e.g., an extract, compound, enzyme or DNA/RNA sequence) or the target of an invention (e.g., a pesticide). Considerable care is required in interpreting whether a species is the source or target of a claimed invention when monitoring utilisation. Passing references to species in patent documents, including in literature references, can provide clues on potential uses of these species even where they are not the source of the claimed invention.

Patent applicants frequently list large numbers of species or make reference to genera or families with the purpose of incorporating all members of a genus or family into the scope of the patent claims. Typically this does not involve the direct collection or use of many of the species listed. This is called essential incorporation. This practice links to the issue of preventing competitors from inventing around a claimed invention and to the well-established doctrine of equivalents in patent law. However, in our view this practice could have significant negative consequences for developing countries seeking to develop their own resources and has anticompetitive consequences.

Patent analysis of this type is one aspect of monitoring under the Nagoya Protocol. Further research is required to develop effective methods for monitoring and promoting transparency in the utilisation of genetic resources outside the patent system.

In practice, there are some limitations when using patent documents for the identification of links with value chains and markets. First, it is time-consuming as there is no standardised methodology or automated tool. Furthermore, this approach mostly allows access to information regarding marketing activities in the business-to-consumer segment, as information is often publicly and readily available. Other types of commercialisation protected through licenses and trade secrets, for example, in the business-to-business segment are difficult to capture because they are seldom publicly available. Additionally, in many cases it is difficult to confirm the presence of a species in a product due to

corporate marketing practices that rarely disclose such information (e.g., rebranding of species-active-molecule trademarks). Also, in some jurisdictions companies are not legally required to disclose the product's list of ingredients. Hence, the monitoring of GR should be carefully considered in ABS contracts and partnerships.

This analysis allows the authors to make some recommendations:

- 1. In some cases, patent activity may involve species that are vulnerable, endangered, or CITES listed. Care is therefore required in assessing the conservation status of species when considering potential opportunities for economic development.
- 2. Enhanced disclosure of the origin of GRand associated TK in patent documents through the inclusion of a declaration or statement on ABSin the description section of patent applications would considerably improve levels of certainty for countries and communities and improve transparency on the utilisation of GRand TK. A statement or declaration on ABS would include basic information on the country of origin, contract, permit, or certificate numbers. A requirement for such a declaration or statement could be incorporated within national/regional ABS frameworks and contractual provisions.<sup>25</sup>
- 3. Companies and research organisations seeking to promote partnerships and demonstrate compliance should consider voluntarily including a statement on ABSin patent applications to demonstrate compliance. Disclosure would also increase the economic or market value of patents based on GR through the increase in legal certainty and the reduction of associated investment risk. Companies and research organisations adopting such practices should receive recognition from partner countries and enjoy reputational gains.

# 3.2 Market opportunities and user institutions' R&D needs and requirements

A range of opportunities where identified across the sectors forms a quantitative and qualitative perspective (section 2.1). This answers two basic questions: what is the R&D intensity and dynamic in the sectors? Where are the valorisation opportunities? Hence, this highlights a major opportunity to engage in scientific partnerships as user institutions become more interested in the scientific information accompanying the GR than the sample itself. This then raises a sub-set of questions for provider institutions in valorising GR and engaging in R&D partnerships with user institutions:

- What are the user institutions' needs and requirements for using GR and for working with an R&D institution in a provider country?
- What are the key drivers of the user institutions' R&D needs and requirements?
- What are the user institutions' R&D processes?

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<sup>&</sup>lt;sup>25</sup> The African Union guidelines on ABS also recommend to include in the Mutually Agreed Terms a clause for the disclosure of the origin of genetic resources and associated traditional knowledge in patent documents.

# What are the key drivers of the user institutions' R&D?

Companies create new products and services in response to a range of social, economic, and environmental challenges.<sup>26</sup> Specific R&D goals and strategies are thus developed. To reduce complexity, four challenges are identified (Table 3). Demographic growth and climate change are overarching. The other two challenges, aging population and unhealthy lifestyle, are specific to mature markets on which the companies mostly concentrate. This is relevant for potential provider institutions in order to appreciate the fit between their research goals and those of the user institutions.

Societal challenge	Description
Demographic growth	The world population is expected to reach 7 to 17 billion people by the end of the century. <sup>27</sup> This brings issues in terms of alimentation, health, and accommodation in a context of limited natural resources.
Climate change	Companies' operations are increasingly affected by climate change such as the availability of raw materials. <sup>28</sup> Some business models are at risk.
Aging population	The world's population is aging, which brings specific diseases (e.g., Alzheimer's, oncology, and rheumatology) and the need for new treatments and products (e.g., complementary diets, anti-aging creams). <sup>29</sup>
Unhealthy lifestyles	Poor nutritional habits and sedentary lifestyles are increasing, among other factors, the prevalence of chronic diseases. <sup>30</sup>

Table 3. Social and environmental challenges that the sectors face

Furthermore a number of drivers guide industry R&D practices. Companies consider the activity of the GR as a priority as well as their access to talent and technology.<sup>31</sup> They take into account a wide range of factors to balance development costs against the predictability of profits.<sup>32</sup> The importance of the regulation on a new ingredient's safety, its integration in R&D, the production and origins of a raw material, if production is required, are becoming key considerations.<sup>33</sup> In an increasingly competitive environment, this leads to various types of R&D organisations and partnerships such as outsourcing.<sup>34</sup>

What are the user institutions' R&D needs and requirements for using a GR and for working with an R&D institution in provider countries?

Companies are increasingly interested in the scientific information accompanying the samples in order to reduce failure rates. Some are increasingly more interested in R&D partnerships than a simple access to a GR. However, user institutions have existing scientific networks and tend to engage in few

<sup>&</sup>lt;sup>26</sup> Science, Technology and Industry Outlook, OECD, 2014. <a href="https://www.keepeek.com/Digital-Asset-Management/oecd/science-and-technology/oecd-science-technology-and-industry-outlook-2014/summary/english\_4b88d3e1-en#page1">https://www.keepeek.com/Digital-Asset-Management/oecd/science-and-technology/oecd-science-technology-and-industry-outlook-2014/summary/english\_4b88d3e1-en#page1 (accessed 15 February 2016)</a>

<sup>&</sup>lt;sup>27</sup> www.unfpa.org/news/10-things-you-didn%E2%80%99t-know-about-world%E2%80%99s-population (accessed 15 February 2016)

<sup>28</sup> www.mckinsey.com/insights/sustainability/how companies can adapt to climate change (accessed 15 February 2016)

<sup>&</sup>lt;sup>29</sup> www.un.org/esa/population/publications/worldageing19502050/ (accessed 15 February 2016)

<sup>&</sup>lt;sup>30</sup> www.who.int/mediacentre/factsheets/fs355/en/www.who.int/ageing/events/world-report-2015-launch/en/ (accessed 15 February 2016)

<sup>&</sup>lt;sup>31</sup> Science, Technology and Industry Outlook, OECD, 2014. <a href="http://www.keepeek.com/Digital-Asset-Management/oecd/science-and-technology/oecd-science-technology-and-industry-outlook-2014/summary/english\_4b88d3e1-en#page1">http://www.keepeek.com/Digital-Asset-Management/oecd/science-and-technology/oecd-science-technology-and-industry-outlook-2014/summary/english\_4b88d3e1-en#page1</a> (accessed 15 February 2016)

<sup>&</sup>lt;sup>32</sup> New nutrition business, 2011.

<sup>&</sup>lt;sup>33</sup> Interviews with R&D experts. op. cit. p. 8.

<sup>&</sup>lt;sup>34</sup> R&D outsourcing in hi-tech industries, A research study. PwC, 2014. <a href="https://www.pwc.com/gx/en/pharma-life-sciences/assets/pwc-r-and-d-outsourcing-in-hi-tech-industries.pdf">https://www.pwc.com/gx/en/pharma-life-sciences/assets/pwc-r-and-d-outsourcing-in-hi-tech-industries.pdf</a> (accessed 15 February 2016)

new R&D collaborations. When they do, provider institutions are evaluated against their ability to understand a user institution's R&D needs and goals and their scientific knowledge of the species.

There are two key success factors to meet user institutions' requirements. First, they consider right at the beginning the support environment of their R&D partner (e.g., commercial, technical) in order to produce an ingredient, should the R&D be successful. Secondly, in order to limit risks and costs, they are looking for existing capacity in the provider country to run pilot tests on a small scale.<sup>35</sup>

### What are the user institutions' R&D processes?

There is a basic R&D process with three phases (i.e., basic research, applied research, market development). Their distinction and sequence can be a grey area due to the diversity of business models, varying degrees of complexity in R&D and the serendipitous nature of discovery. This framework allows the further analysis of the complexity of a user institution's R&D processes. For instance, an R&D process can take a few years in the functional food arena and up to two decades in the pharmaceutical. This type of information is useful to identify the phases remaining to complete the R&D and the level of investment needed before a product or service can be marketed.

# 3.3 Readiness of the R&D institutions to create and grasp opportunities

The identification and examination of the most relevant actors for each country highlight a range of common and country-specific characteristics. In particular, the strengths and potential weaknesses in the valorisation of GR as well as some gaps with user institutions' R&D requirements have been identified.

This section provides an overview of the national landscape of actors valorising and/or utilizing GR in the countries covered by this report. On average, 55 actors were identified per country. Of these, on average, 33 were selected as the most relevant to the utilisation of GR and were further examined. However, due to the limited information found, it was not possible to examine the specific areas of research undertaken or their capacity to utilize GR (e.g., human, technical, know-how). Although all these actors are involved in activities related to the valorisation of biological resources, in most cases, it is unclear whether and how they utilize GR.

## Characteristics common to the six countries

Kenya and South Africa have a national valorisation strategy in place, aligned with their development goals. They also have a large and diversified network of R&D actors. Cameroon, Madagascar and Senegal have a few but experienced actors, mostly public ones, in research (e.g., L'Institut fondamental d'Afrique noire, Senegal) and/or bioprospecting (e.g., Centre National d'Application de la Recherche Pharmaceutique, Madagascar). In these three countries, the capacity to transit from the research to the development phase seems rather limited. This can be explained by a doctrinaire approach focusing on research and by the absence of actors in the development phase. Furthermore, a national strategic approach to the valorisation of GR is not apparent. In the case of Mozambique, although it shares

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<sup>&</sup>lt;sup>35</sup> Interviews with R&D experts. op. cit. p. 8.

similarities with the previous countries, a strategic focus has been given to marine GR and biotechnology (e.g., Institute of Marine Biotechnology).

# Strengths

There are common strengths across the six countries. In most countries, there is a multi-stakeholder initiative related to R&D in place involving foreign actors (e.g., Le Pôle de compétence en partenariat Grand Sud, Cameroun). This demonstrates the national actors' capacity to collaborate, which is key to the valorisation of GR as no single actor can contribute to the whole R&D process. There are foundations for further identifying synergies and partnerships as foreign R&D actors are operating in the countries (e.g. L' Institut de recherche pour le développement (IRD) in Senegal).

Finally, in all countries a few actors seem to contribute and/or support the valorisation of biological resources and possibly GR. This often includes collaborations with foreign development agencies on value chains (e.g., the Centre for the promotion of Agriculture, Mozambique). However, as limited information was found overall, it is difficult to draw any conclusions regarding the potential effectiveness of these actors in the valorisation of GR.

# Challenges

There are common challenges and potential weaknesses across the six countries. The collective capacity of the actors to partner and intervene on the whole R&D process, from sampling to setting up a value chain for a marketed ingredient, is generally very limited.

In general, there is a limited support environment for institutions that valorise GR. Few actors doing taxonomy could be identified, although it is a basic and key step of the R&D process. This is highlighted as a major constraint by user institutions across the sectors. There is also limited valorisation of associated TK. Considering the relatively high number of references to TK in the patent documents, this could be considered a lost opportunity.

### Towards a valorisation framework

Key elements of an institutional set up for the effective and efficient valorisation of GR were identified in this report. It comprises two main categories: a framework for ABS and the valorisation of GR, and the availability and capacity of the domestic R&D actors. This is based on empirical features identified from South Africa and Kenya:

- R&D partnerships are encouraged through research councils and a wide range of initiatives and fora
- Many R&D collaborations are with foreign actors
- A conducive support environment exists, including a national bioeconomy or bioprospecting strategy and a business incubation association
- The role of trade associations serving different end markets (e.g., natural ingredients in food, cosmetics, and health biotechnology).

Table 4 below presents a high level assessment of each country's position against these categories. A classification was devised to indicate the extent to which these key factors are implemented using a basic categorisation: in place (colour code: green) / non-functional (colour code: red)/ in development (colour code: orange). In light of the information available, it is impossible to come to any definite conclusions. However, this can be used as a basis for further analysis to clarify the country's strengths and weaknesses.

		Cameron	Kenya	Madagascar	Mozambique	Senegal	South Africa
	Integration of ABS in the						
	country's development and						
	conservation goals						
	ABS framework with clear						
National	procedures						
framework	Valorisation strategy for genetic						
on ABS and	resources (e.g., at biodiversity or						
valorisation	sector level)						
of GR	Valorisation strategy for						
OT GR	traditional knowledge						
	Conducive business environment						
	and support system						
	Country's experience on						
	bioprospection						
	Formal providers of GR identified						
	Availability of actors with						
	capacity (e.g., depth and breadth)						
	to carry R&D (e.g., universities,						
	companies, NGOs)						
Actors	Alignment of national research						
related to	with users' R&D needs						
R&D on GR							
	research to the development						
	phase						
1	Actors doing biodiversity						
1	inventory and taxonomy						
1	Bioprospecting program						
1	Diversity of foreign actors doing						
	R&D in the countries						

Table 4. Strengths and weaknesses across the six countries for the valorisation of GR

# 3.4 Challenges for PIC and MAT to facilitate the valorisation of GR

Interviews with user institutions allowed us to identify three basic challenges that deter or slow down ABS agreements. This issue is relevant for provider countries willing to facilitate access to GR in order to gain benefits in a fair and equitable manner.

The lack of legal certainty and unclear scope for GR access and utilisation is fuelled by a lack of understanding by providers of the user institutions' practices and business models and by the user institutions' difficulty in navigating some complex regulatory environments and in meeting various expectations. This leads to mutual mistrust and high transaction costs. In all cases, the understanding of the user institution's R&D needs and goals is paramount.

The development and implementation of ABS agreements should reflect sectoral specificities including existing practices on sustainability, transparency, and the sharing of various types of benefits.<sup>36</sup> Often restrictive guidelines are eased or reversed after the partnership has had time to develop. A willingness to work within the country's requirements and to find workable solutions to respect them, without forcing the issues initially, has been a successful strategy within the International Cooperative

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<sup>&</sup>lt;sup>36</sup> S. Benard, Director of the Environment, LVMH, 2012. Pers. Comm.

Biodiversity Groups (e.g., export of self-replicating organisms, export of DNA, etc.). This requires flexibility, ingenuity, and patience on all sides. Similarly, countries must respect the confidentiality issues of the private sector and find creative solutions to work within those constraints while still obtaining some level of data on the use of their GR.<sup>37</sup>

In this context, potential solutions are suggested.

- **Simple access to information** (e.g., a national focal point, a competent national authority) with clear timelines and efficient procedures in order to improve transparency and simplicity.<sup>38</sup>
- **Simple guidelines** could be provided for the development of ABS agreements. A regular review would then allow for their improvement. The priority is to get started with experimental cases and to learn from them.<sup>39</sup>
- Partnerships between provider and user institutions, with regular dialogues to exchange information, is another solution as trust takes time to develop.<sup>40</sup>
- The legal obligations to disclose origin and/or source of GR in patent applications for significant markets (e.g., some European countries, India, Brazil and China) could contribute to building trust.<sup>41</sup>
- Model clauses pre-approved by the government could be used more easily by some user and provider institutions.<sup>42</sup>
- **Trusted third parties**, acting as intermediaries, could ensure continuous communication between the user institution, the provider institution, and the provider government.<sup>43</sup>
- A two-phase approach in the ABS authorisation process (i.e., basic research and commercial development), with a commercial trigger that activates a second round of negotiation around the specific product or service outcome. In this approach, initial agreements should focus on more near-term and deliverable benefits such as training, technology transfer, and research opportunities.<sup>44</sup> However, some companies prefer a unique PIC and MAT without having to renegotiate.
- There is a need to find a balance between specific and flexible ABS requirements that trigger
  the sharing of benefits. The market share of a finished product is a potential indicator of
  success. However, it does not inform providers on the contribution of the new ingredient in
  the marketing success (e.g., functional ingredients).<sup>45</sup> Two other indicators can be considered:
  - a. Changing the goal of the R&D in the early research phase and

 $<sup>^{</sup>m 37}$  F. N. Katz, Fogarty International Center National Institutes of Health, 2013. Pers. comm.

<sup>&</sup>lt;sup>38</sup> 3rd ABS Business Dialogue Public-Private Partnerships for Sustainable Development, GIZ. 2014

<sup>&</sup>lt;sup>39</sup> P. André, Director Cosm'ethic (former Director of Botanical Innovation, LVMH), 2014. Pers. Comm.

<sup>&</sup>lt;sup>40</sup> 3rd ABS Business Dialogue Public-Private Partnerships for Sustainable Development, GIZ. 2014

<sup>&</sup>lt;sup>41</sup> G. Burton, Adjunct Senior Fellow of the United Nations University (UNU), 2014. Pers. Comm.

<sup>&</sup>lt;sup>42</sup> B. David, Institut de Recherche Pierre FABRE, 2013. Pers. Comm

<sup>&</sup>lt;sup>43</sup> G. Burton, Adjunct Senior Fellow of the United Nations University (UNU), 2014 Pers. Comm.

<sup>&</sup>lt;sup>44</sup> F. N. Katz, Fogarty International Center National Institutes of Health, 2013. Pers. comm.

 $<sup>^{45}</sup>$  X. Brochet, Head of Natural Ingredient Innovation, Firmenich, 2015. Pers. Comm.

- b. The collection and recollection of samples (e.g., what does this tell about product development?).
- It is, however, unclear if a patent is a good trigger point, as it may come quite early in the innovation process when the final product or service is still uncertain and its corresponding possible value is not known.

# Recommendations

The report "Economic potential and valorization opportunities of genetic resources under the Nagoya Protocol in Africa" shows that there is on-going R&D and investment in the biodiversity of the six countries and that GR are of value for actors doing R&D across different sectors. There are potential valorisation opportunities for GR. They require a pragmatic approach to unlock this potential.

Overall, this report raises two main questions for public policy on ABS and the valorisation of GR. First, in practice, how to close the R&D gap between providers and user institutions in order to take advantage of the valorisation opportunities related to GR? Second, what are the policy needs to create a favourable institutional and business environment in order to facilitate access to GR and share in a fair and equitable manner the benefits arising from their utilisation?

There is dense literature on measures to stimulate innovation policy and tools. For instance, the actions targeting knowledge diffusion and absorption are just as important as investment in knowledge generation. He with regard to sustainable development matters, such as ABS, a main challenge is to navigate through complexity by strengthening impact assessment and institutional capacities to identify and drive reform priorities. This includes paying greater attention to the stakeholders' needs. He

In this context, general recommendations are presented in this synthesis, while specific country recommendations are made in the respective valorization potential assessments, where relevant.

# Closing the R&D gap: Focus on domestic strengths aligned with relevant user institutions R&D needs

The principle to be applied is to align core national domestic R&D strengths with relevant user institution's R&D needs to uncover valorisation opportunities for GR. While the development of a valorisation strategy for GR can be a long-term endeavour, a focus on realistic R&D activities that can be undertaken in the short to medium term and that meet specific national R&D needs is recommended. This should be aligned with countries' development objectives. In this context, the following steps can be undertaken at various scales (e.g., national, regional, industry, and cluster).

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<sup>&</sup>lt;sup>46</sup> Science, Technology and Industry Outlook, OECD, 2014

 $<sup>^{</sup>m 47}$  Regulatory Policy and the Road to Sustainable Growth, OECD, 2010

# Identify the capacities and support needs of the domestic R&D institutions.

Before engaging with user institutions, it is necessary to gain a solid understanding of the landscape of the country's actors related to R&D, the scope of their R&D capacities and their related support needs. For instance, what are the priority research areas within the country's universities? What are the domestic private actors' and NGOs' R&D objectives?

# Clarify market opportunities and user institutions' R&D requirements.

The understanding of market trends is the basis for identifying potential valorisation opportunities for GR. It should be noted that national and regional markets are often easier to exploit and provide shorter returns than international ones. A key feature of this analysis is clarification of the foreign users' R&D needs and requirements that would enable a domestic R&D actor to enter their R&D process as well as sharing in any potential gains and benefits. In this context, business and trade organisations could be further encouraged to be active on the valorisation of biodiversity and GR.

The understanding of the links between patent documents, value chains, markets for species of economic interest, as well as case studies, can be a useful source of information. For instance, how were the GR accessed, and what specificities did the domestic actors bring to the R&D process?

# Target valorisation opportunities, leverage strengths and engage in R&D partnerships.

Key valorisation opportunities should be identified as a synthesis of the strengths, weaknesses, opportunities, and threats (SWOT) analysis. Analysis should confirm the match between the domestic R&D strengths and the market opportunities. In this context, support for the development of partnerships between domestic actors and foreign user institutions should be encouraged. As provider R&D institutions tend to have limited financial resources, the strategic communication of scientific results in industry and public research networks appears as a pertinent tool.

Implement an environment that facilitates access for targeted user institutions and promotes benefits

Key elements of such an environment include:

# 1) A supportive environment to leverage national strengths on R&D

Initially, this may call for a mechanism or forum to facilitate exchange of information with a view to reinforce the R&D strengths and also address weaknesses. For instance, lessons could be learned from the existing bioprospecting experiences. In time, capacity can be developed to handle different types of R&D partnerships and to support those that are aligned with national development goals.

# 2) Simple, clear, and flexible ABS procedures to accommodate different type of user institutions

Considering the low chances of R&D leading to the actual commercialisation of a product or a service, access to GR should be adapted and proportionate to various user institutions' needs. For instance, consideration could be given to the development of access procedures that take into account the specificities of sectors and the type of R&D actors (e.g., small, large, public, private). Different types of contracts could be considered in light of their adaptation to the specificities of the R&D project. A clear framework, taking into account a country's development goals, including conservation of biodiversity, would facilitate exchanges with potential user institutions.

# 3) The targeting of benefits that allows the domestic actors to move up the value chain

As most GR only undergo the initial stages of the research phase (e.g., screening), where the occurrence of failure is high, the requirements for benefit-sharing should be realistic and proportionate with the level of R&D investment of the institutions. The alignment with national development, R&D, and valorisation goals should be considered. In many cases there is space for creativity.

# 4) Valorise traditional knowledge

TK does appear as a potential source of valorisation of species. A specific valorisation approach may be necessary. Some first steps could be to map the holders of such knowledge (with their collaboration) and the knowledge widely available or already scientifically documented. Eventually, the aspirations of the holders of TKin sharing and valorising their knowledge should be clarified.

# 5) Monitoring R&D practices

Publicly available information is often incomplete and does not provide a comprehensive picture of the use of GR in R&D processes. Furthermore, valorisation activities in the business-to-business segment are almost invisible. This may call for specific requirements to monitor GR along the value chain and in the markets.

Policy makers may wish to build on these recommendations when updating or developing national ABS frameworks so that they can contribute to the valorisation of their GR.

Annex 1: Kenyan species subject to a patent document that may have wider economic potential

## - Acokanthera ouabaio:

"A research showed that the extracts of Acokanthera schimperi and Euclea schimperi showed **antiviral activity** against coxsackievirus B3 (CVB3), influenza A virus and herpes simplex virus type1 Kupka (HSV-1). Thus, this supports their traditional use in the treatment of skin diseases of viral origin" (Gebre-Mariam et al., 2005).

## - Actinomadura kijaniata:

There is research on the species in areas such as its **antibiotic and antiviral properties** (Betzer et al., 2001). A sponsor of this research is Aventis. There is no information to connect it with the development of a medicine. Another area of research is the **biodegradation of plastics by microorganisms and enzymes** (Tokiwa Y., 2009).

## Natrialba magadii; Natronobacterium magadii:

There is extensive research on the species in the field of **production of microbial fuel**. For instance, the Joint Genome Institute (Department of Energy, USA) sought to sequence the species in 2008.<sup>48</sup> It further notes that "Natrialba magadii is an extremophile in the extreme. It thrives in alkaline hypersaline conditions (pH 9.5, 3.5 M NaCl) and encodes enzymes that are not only salt tolerant but also often tolerant of high pH, high temperatures, and the presence of solvents," which seems highly relevant to the current R&D needs in the biotechnology industry. Other recent scientific publications include Siddaramappa S, Challacombe JF, De Castro RE, Pfeiffer F, Sastre DE, et al. (2012), and Ordóñez MV., et al. (2012).

# Wigglesworthia glossinidia:

There is important research on the species. Scientists are currently looking into ways that **tsetse fly** populations could be controlled or eliminated by taking advantage of its reproductive reliance on "W. glossinidia". The World Health Organisation indicates<sup>49</sup>: "Recent advances in molecular technologies and the availability of genomic information could lead to the development of new control strategies aimed directly at the fly or its parasite transmission ability. Genomics of tsetse symbiotic bacteria are of interest since in the absence of their gut flora, tsetse flies are severely impaired in their longevity and reproduction. Two bacteria have been implicated in modifying vector competence of their host (Sodalis golssinidius and Wigglesworthia glossinidia)." Further scientific literature is indicated in Annex 5.

### - Zanthoxylum qilletii:

"The genus Zanthoxylum has been recognised for a number of biological activities like allelopathic activity, analgesic activity, anticonvulsant activity, anthelmintic activity, anti-inflammatory activity, antimicrobial activity, antinociceptive activity, antioxidant activity, antiparasitary activity, antiplatelet activity, citotoxic activity, trypanocidals activity, antileishmanial activity, anticestodal property,

<sup>48</sup>http://jgi.doe.gov/why-sequence-natrialba-magadii/

<sup>49</sup>www.who.int/trypanosomiasis african/vector control/en/

gastroprotection activity, anti-sickling activity, hypnotic activity etc. A few species of the genus have been recommended as dietary supplements to protect against emergent diseases such as cardiovascular problems, cancer and diabetes. Different parts of Zanthoxylum have been popularly used traditionally in different ethno medicines for different ailments." (Medhi et al., 2013)

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