# Global Environmental Law and Policy

# A Regional Review of Genetic Resource Access and Benefit Sharing: Key Issues and Research Gaps

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Abstract. Countries are increasingly using access and benefit sharing (ABS) as a legal mechanism to support the conservation and sustainable use of the world's biological diversity. ABS regulates collection and/or use of genetic resources/traditional knowledge and sharing benefits from their use with the provider. The purpose of this review is to assess the trends, biases and gaps of ABS literature using a regional comparative approach about the key topics of concern between each region. It analyses four key topic groupings: (1) implementation of international, regional and national ABS policy and law; (2) intellectual property and ABS; (3) traditional knowledge; and (4) research, development and commercialisation. Findings included gaps in: (1) analysing effectiveness of national level implementation; (2) addressing apparent conflicts between support for intellectual property promoting exclusivity for traditional knowledge and challenges to intellectual property exclusivity for patents; (3) examining traditional knowledge of local communities (in contrast to Indigenous Peoples); and (4) lack of practical examples that quantify benefit sharing from research and commercialisation outcomes. We conclude that future research addressing the identified gaps and biases can promote more informed understanding among stakeholders about the ABS concept and whether it is capable of delivering concrete biological conservation, sustainable use and equity outcomes.

Keywords: Access and benefit sharing, convention on biological diversity, traditional knowledge, biodiversity

#### 1. Introduction

Access and Benefit Sharing (ABS) is a legal approach and framework for regulating the access and use of genetic resources and associated traditional knowledge and the fair and equitable sharing of the benefits from their use with the provider of the resources and knowledge. ABS is increasingly being used by countries as an economic tool for the conservation and sustainable use of genetic resources and addressing international commitments to delivering on the United Nations' (UN) Sustainable Development Goals. The ABS approach originated from the UN Convention on

The CBD and its implementing instrument, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits

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Biological Diversity (CBD), which recognises countries' sovereign rights over the genetic resources within their jurisdiction. The ABS concept is increasingly spreading to a range of forums that deal with genetic resources within and beyond national jurisdictions. These include the World Health Organization (concerning virus genetic resources), the Food and Agriculture Organization (concerning genetic resources for food and agriculture) and deliberations under the Convention on the Law the Sea (concerning marine genetic resources in areas beyond national jurisdiction.<sup>2</sup>

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Arising from their Utilization to the Conservation on Biological Diversity (Nagoya Protocol), are international agreements that outline an ABS framework for genetic resources within national jurisdictions. These agreements apply generally to 'genetic resources', which are 'genetic material' of actual or potential value, i.e. 'any material of plant, animal, microbial or other origin containing functional units of heredity' (CBD Article 2). Other international treaties and agreements that regulate or affect the sharing, transfer and access to genetic resources include the Food and Agriculture Organization of the UN International Treaty for Plant Genetic Resources for Food and Agriculture (Plant Treaty), World Trade Organisation's Trade Related Impacts of Intellectual Property Rights (TRIPS) and the UN World Health Organization's Pandemic Influenza Preparedness Framework (PIP Framework).

Regional frameworks for ABS strengthen implementation across national boundaries of neighbouring countries that often have similar geographical and biological characteristics, but diverse capacities for implementing and enforcing biodiversity measures. The first regional approach was the Andean Pact Decision 391 (Bolivia, Colombia, Ecuador, Peru and Venezuela) that established a legal framework regulating access to the genetic resources of the member countries to create conditions for the fair and equitable sharing of benefits arising from their use and promote the consolidation/development of scientific and technical capacities at local. national and subregional levels, among other things (Article 2). More recent approaches include the 2015 African Union Strategic and Practical Guidelines for the Coordinated Implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation<sup>3</sup> that builds on the 2000 Model Law that was used by several member countries to develop their national laws.4 The European Union has a due diligence framework for member countries and other regions have ad hoc guidance documents, which are mentioned in section 3.2 below.

The Philippines was the first country to introduce national ABS laws.<sup>5</sup> To date there are at least 62 countries with dedicated ABS laws and many other countries with ABS measures.<sup>6</sup> Other countries have draft ABS laws or have a patchwork of laws that regulate the collection of plants and animals that might have benefit sharing elements.<sup>7</sup> National

laws vary significantly in their geographical, subject matter, activity and temporal scope as well as their administrative processes, prior informed consent, benefit sharing and enforcement procedures.<sup>8</sup>

While ABS measures/frameworks currently exist at international, regional and national levels, ABS will have a range of impacts and can raise unique concerns for different regions. Consequently, this article takes a regional comparative approach to ABS of genetic resources to better identify and examine overarching key issues across regions and kev differences between them. The article systematically reviews the peer-reviewed ABS literature about genetic resources, associated information and associated traditional knowledge to assess the trends and gaps in key knowledge areas covered in each region. The key topics concern: implementation of international, regional and national ABS policy and law; intellectual property; traditional knowledge and research, development and commercialisation. This information is critical for understanding the gaps in environmental policy and law analysis relating to ABS as a tool for biodiversity conservation and sustainable use.

#### 2. Methods

# 2.1. Systematic Quantitative Literature Review

The global and regional-level reviews use a Systematic Quantitative Literature Review (SQLR) method described by Pickering and Byrne (2014)<sup>9</sup> to assess the literature on ABS in relation to genetic resources. This method falls between a traditional narrative review and a meta-analysis. systematically identifies peer-reviewed literature from online databases and quantifies the data, showing trends, biases and key concerns at the regional level. The regions analysed were Africa, Asia, Europe, North America, Oceania and South America. We only found four publications in English relating to the Middle East (only relating to Syria). As this is a relatively low number of articles, we have not included an analysis of the Middle East as a distinct geographic region.

In this review we examine ABS in relation to all genetic resources. A detailed review of ABS in relation to aquatic genetic resources (including aquaculture, marine genetic resources in Areas Beyond National Jurisdiction, etc.), and in relation

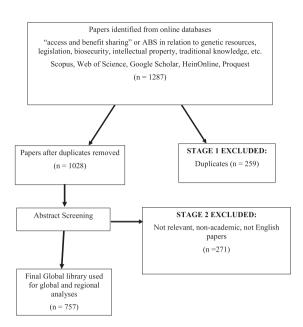


Fig. 1. Preferred Reporting Items for Systematic Review Recommendations (PRISMA) flowchart outlining the process for compiling this review (modified from Moher, D., Shamseer, L., Clarke, M., Ghersi, D., Liberati, A., Petticrew, M.,... Stewart, L. A. (2015). Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic Reviews, 4(1), 1-9). n = number of articles.

to the aquaculture sector has already been conducted in Humphries et al. (2018)<sup>10</sup> and Humphries et al. (2021)<sup>11</sup> respectively. This review discusses taxa to the extent that it is relevant to the key themes of ABS.

Rather than a traditional narrative approach with the associated in-depth analysis of the findings and conclusions of each ABS publication, the SQLR summarises the status of the literature so that the results are reliable, quantifiable and reproducible. By providing a commentary on the literature, the SQLR highlights knowledge gaps and reasons why more research is needed to fill them. The data collection methodology is described in more detail below and is summarised in Fig. 1.

#### 2.2. Data Collection

We searched five commonly used databases for this field (Scopus, Web of Science, Proquest, Google Scholar, HeinOnline) for articles relating to access and benefit sharing published between January 1980 and December 2019. Our initial search used the search term [("access and benefit\*shar\*173") AND ("genetic resources" OR law OR legislation OR policy OR "transfer

agreement" OR biosecurity OR biosafety OR "intellectual property" "traditional OR knowledge")]. We limited our search to journal articles, books, book chapters, and early access papers (excluded grey literature, editorials, comments, reviews, white papers, conference proceedings) published in English. We entered the results from all five databases into a single Endnote library (n=1287). We then excluded duplicate references and unrelated or irrelevant articles (n=530). Examples of exclusions were (i) articles where only title, abstract and key words were in English; (ii) non-academic articles, e.g. editorials, conference reviews, grey literature; (iii) articles where ABS is only included in the discussion as a need for further research or might be applied to the review topic field; (iv) articles that discuss ABS generally but did not focus on specific relevant issues, e.g. legislation, implementation, policy, or are related to genetic resources, intellectual property, traditional knowledge or biosecurity; and (v) articles where ABS was only used in keywords and/or references. The final global library contained 757 articles. This library (the 'global library') was used to examine global and regional patterns and trends.

# 3. Results

#### 3.1. Geographic Patterns in ABS

Most of the 757 articles in the final ABS library were focused at the global level, incorporating multiple geographic regions (426, 56.2%) (Table 1). Articles focused on the Asian (113, 14.9%), African (91, 12%) and European (57, 7.5%) regions made up the majority of the remaining articles. Relatively few articles were from North and South America (<5% each, Table 1). The individual country with the most articles published on ABS in relation to genetic resources was India (58, 7.7%), followed by Australia and South Africa (each with 23 articles, 3%) (Table 1, Fig. 2). Of the 77 individual countries in the global library, 52 (67%) had fewer than five articles published in relation to ABS of genetic resources.

#### 3.1.1. Africa

Of the 91 articles focusing on Africa, 34 (37.4%) were on the African region as a whole or included

Table 1

Summary of global literature search results on access and benefit sharing (ABS) in relation to genetic resources. Note, categories are not exclusive. IP=Intellectual Property, Law=national legislation, Policy=International/regional policies or treaties e.g. CBD, TRIPS, TK=Traditional Knowledge. Regional papers are focused on the whole region or multiple countries within the region

	All papers	Global level only	Africa	Asia	Europe	Oceania	North America	South America
N papers (% of total)	757 (100%)	426 (56.2%)	91 (12%)	113 (14.9%)	57 (7.5%)	43 (5.7%)	29 (3.8%)	35 (4.6%)
N regional papers (%)	75 (10%)	N/A	34 (37.4%)	8 (7.1%)	22 (38.5%)	5 (11.6%)	2 (6.9%)	4 (11.4%)
N individual country papers (%)	242 (34%)	N/A	57 (62.6%)	105 (92.9%)	35 (61.4%)	38 (88.4%)	27 (93.1%)	31 (88.6%)
Number of key topics covered	19	19	15	16	15	15	13	13
Taxa covered								
Animal	44 (5.8%)	28 (6.6%)	5 (5.5%)	5 (4.4%)	4 (7%)	1 (2.3%)	1 (3.4%)	0
Fungi	1 (0.1%)	0	0	1 (0.2%)	0	0	0	0
Microbe	14 (1.8%)	11 (2.6%)	0	0	2 (3.5%)	0	1 (3.4%)	0
Plant	248 (32.8%)	118 (27.7%)	46 (50.5%)	38 (33.6%)	6 (10.5%)	16 (37.2%)	11 (37.9%)	13 (37.1%)
Not specified	473 (62.4%)	269 (63.1%)	40 (44%)	69 (61.1%)	39 (68.4%)	26 (60.5%)	16 (55.2%)	22 (62.8%)
Top 5 topics (N, %)	Policy	Policy	Policy	Policy	Policy	Policy	Policy	Policy
	(617, 81.5%)	(383, 89.9%)	(60, 65.9%)	(80, 70.8%)	(50, 87.7%)	(27, 62.8%)	(17, 58.6%)	(17, 48.6%)
	IP	IP	TK	IP	Research	TK	IP	IP
	(284, 37.5%)	(165, 38.7%)	(46, 50.6%)	(52, 46%)	(11, 19.3%)	(22, 51.2%)	(13, 44.8%)	(17, 48.6%)
	TK	TK	IP	TK	Law	IP	TK	TK
	(240, 31.7%)	(106, 23.5%)	(34, 37.4%)	(45, 39.8%)	(8, 14%)	(15, 34.9%)	(11, 37.9%)	(14, 40.6%)
	Bio-	Bio-	Law	Law	IP	Bio-	Biobank	Bio-
	prospecting	prospecting				prospecting		prospecting
	(112, 14.8%)	(64, 15%)	(24, 26.4%)	(35, 31%)	(7, 12.3%)	(7, 16.3%)	(3, 10.3%)	(6, 18.8%)
	Law	Law	Bio-	Bio-	Biobank	Law	Biopiracy	Law
			prospecting	prospecting				
	(86, 11.4%)	(48, 11.3%)	(15, 16.5%)	(14, 12.4%)	(7, 12.3%)	(6, 13.9%)	(3, 10.3%)	(4, 12.5%)
Most common individual	India	NA	South Africa	India	Norway	Australia	USA	Brazil
country (N, %)	(58, 7.7%)		(23, 25.3%)	(58, 51.3%)	(10, 17.5%)	(23, 53.5%)	(18, 62.1%)	(10, 28.6%)

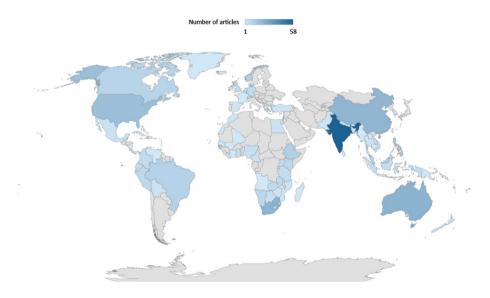


Fig. 2. Number of articles on genetic resource ABS in each country (n = 331).

multiple African countries (Table 1). The other articles examined ABS in relation to genetic resources in 24 individual African nations (see Supplementary Material). Most articles focused on countries in eastern (45, 49.4%), southern (37, 41%) western (15, 18%) Africa with few articles from northern (5, 6%) or central Africa (4, 5%) (Fig. 2). When we take into account the number of countries in each region, we can clearly see that there are proportionately more articles from southern Africa (average = 7 articles/country) than any other region (average range 0.4-2.2/country). This is primarily due the large number of articles focusing on South Africa (23, 25%). Of the 24 countries, 16 (67%) had fewer than 5 articles published in relation to ABS of genetic resources.

#### 3.1.2. Asia

Of the 113 articles focusing on Asia only eight (7.1%) were on the Asian region as a whole (Table 1). The other articles examined ABS in relation to genetic resources in 17 nations (Fig. 2, Supplementary Material), particularly India (58, 51%), China (22, 19.4%) and the Philippines (15, 13.3%). Most articles focused on countries in southern (66, 61%) or south-eastern (39, 36%) Asia with fewer articles from eastern Asia (26, 24%). When we take into account the number of countries in each region, there are proportionately more from articles southern Asia (average = 6.6)articles/country) than the other regions (average range 3–3.3/country). This is primarily due the large number of articles focusing on India (58). Of the 17 countries, 12 (71%) had fewer than five articles published in relation to ABS of genetic resources.

# 3.1.3. Europe

Of the 57 articles focusing on Europe, 22 (38.5%) were on the region as a whole usually in relation to the European Union (Table 1). The other articles examined ABS in relation to genetic resources in 12 European nations (eight EU member countries, four non-members) (Fig. 2, Supplementary Material). With the exception of Norway (10, 17.5%), the UK (6, 10.5%) and Germany (6, 10.5%), all countries had fewer than five articles relating to ABS of genetic resources at the national level.

#### 3.1.4. North America

Only two countries are included in the North America region – the United States and Canada. Of the 29 articles focusing on this region, 18 were on the United States, nine were on Canada, and two articles focused on ABS in relation to genetic resources in the region as a whole (Table 1, Fig. 2).

#### 3.1.5. Oceania

Most of the 43 articles from the Oceania region focused on Australia (23, 53.5%) (Table 1, Fig. 2). The remaining articles examined ABS in relation to genetic resources in nine other nations (Supplementary Material) with five articles on the region as a whole. Of the 10 countries represented, eight (80%) had fewer than five articles published on ABS of genetic resources.

#### 3.1.6. South America

Of the 35 articles focusing on South America only four (11%) focused on the region as a whole (Table 1). The other articles examined ABS in relation to genetic resources in 11 nations (Fig. 2, Supplementary Material), particularly Brazil (10, 29%), Peru (7, 20%) and Colombia (6, 17.1%). Most articles focused on continental South America (34, 97%) with only one article on island nations (Cuba).

## 3.2. Key Themes in ABS

There were 19 key topics relating to ABS of genetic resources reported by the articles in the global library with most articles covering multiple topics. These most common topics for each region are summarised in Table 1, while a more detailed breakdown of the results is presented in Table 2. The most common topics for South America, Oceania, Asia and Africa were: policy (international and regional frameworks); intellectual property; traditional knowledge; bioprospecting; and national laws. The most common topics for Europe and North America were policy, intellectual property, research, bioprospecting, biopiracy and biobanks.

The key topics were grouped into four major themes which are outlined and discussed below (Table 2). The topic of policy (international and regional frameworks) has been merged with the category of national laws under the theme 'ABS policy and law' because of the content overlap of these topics. Three other specific themes analysed below are intellectual property, traditional knowledge and research. 'Research' encompasses topics of commercial research (classified as 'bioprospecting'), non-commercial research and biobanks. There are some articles that look at ABS

Table 2

Summary of key topics relating to ABS of genetic resources globally and in each region. ABS = access and benefit sharing, CC = climate change, Certificate = Certificate of origin, IP = Intellectual Property, Law = national legislation, MTA = Material Transfer Agreements, PIC = Prior Informed Consent, Policy = International/regional policies or treaties, e.g. CBD, TRIPS, TK = Traditional Knowledge. Note, categories are not exclusive

Торіс	All (n = 757)	Africa (n = 91)	Asia (n = 113)	EU (n = 57)	Oceania ( <i>n</i> = 43)	North America (n = 29)	South America $(n = 35)$
Theme 1 ABS Policy and Law							
ABS	9 (1.2%)	1 (1.1%)	2 (1.8%)	1 (1.8%)	1 (2.6%)		13 (37.1%)
Certificate	11 (1.5%)	2 (2.2%)	1 (0.9%)	2 (3.5%)	1 (2.6%)	1 (3.4%)	1 (2.9%)
Law	86 (11.4%)	24 (26.4%)	35 (31%)	8 (14%)	6 (13.9%)	2 (6.9%)	4 (12.5%)
MTA	24 (3.2%)	3 (3.3%)	1 (0.9%)	1 (1.8%)	1 (2.6%)	1 (3.4%)	
PIC	19 (2.5%)			1 (1.8%)	1 (2.6%)		1 (2.9%)
Policy	617 (81.5%)	60 (65.9%)	80 (70.8%)	50 (87.7%)	27 (62.8%)	17 (58.6%)	17 (48.6%)
Theme 2: Intellectual Property							
IP	284 (37.5%)	34 (37.4%)	52 (46%)	7 (12.3%)	15 (34.9%)	13 (44.8%)	17 (48.6%)
Theme 3: Traditional Knowledge							
Biopiracy	27 (3.6%)	4 (4.4%)	3 (2.7%)		1 (2.6%)	3 (10.3%)	2 (5.7%)
TK	240 (31.7%)	46 (50.5%)	45 (39.8%)	4 (7%)	22 (51.2%)	11 (37.9%)	14 (40.6%)
Theme 4: Research, Development and							
Commercialisation							
Biobank	50 (6.6%)	4 (4.4%)	1 (0.9%)	7 (12.3%)	2 (5.3%)	3 (10.3%)	2 (5.7%)
Bioprospecting	112 (15%)	15 (16.5%)	14 (12.4%)	5 (8.8%)	7 (16.3%)	1 (3.4%)	6 (18.8%)
Biotechnology	38 (5%)	5 (5.5%)	5 (4.4%)				1 (2.9%)
Research	57 (7.5%)	1 (1.1%)	3 (2.7%)	11 (19.3%)	4 (10.5%)	3 (10.3%)	3 (8.6%)
Technology	6 (0.8%)		1 (0.9%)				
Other key topics							
Biocontrol	6 (0.8%)			1 (1.8%)	1 (2.6%)	1 (3.4%)	
Biosecurity	4 (0.5%)		2 (1.8%)	1 (1.8%)		1 (3.4%)	
CC	7 (1%)	4 (4.4%)					
Conservation	47 (6.2%)	7 (7.7%)	4 (3.5%)	4 (7%)	3 (7.5%)		1 (2.9%)
Food security	35 (4.6%)	4 (4.4%)	4 (3.5%)	1 (1.8%)	1 (2.6%)	1 (3.4%)	
N topics	19	15	16	15	15	13	13

in the broader context as a framework and strategy for promoting the conservation and sustainable use of genetic resources, including climate change, food security, conservation, biocontrol and biosecurity. While important in the overall context of ABS of genetic resources, given the diversity of coverage, we do not discuss these articles in detail in this paper (see Other Theme in Table 2 for summary).

#### 3.2.1. Theme 1: ABS Policy and Law

International or regional policies, conventions and treaties were the focus of more than 80% of all the articles in the global library (617 articles). These included:

- Convention on Biological Diversity (CBD);
- Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol);

- International Treaty on Plant Genetic Resources for Food and Agriculture (Plant Treaty); and
- World Health Organization's (WHO) Pandemic Influenza Preparedness Framework (PIP Framework).

The CBD and its implementing agreement the Protocol establish Nagoya an international framework for their Contracting Parties that takes a bilateral approach to ABS. Under this approach, administrative decisions about access and use are binding through domestic permits or authorisations that demonstrate prior informed consent of the provider of the genetic resource and/or traditional knowledge. Arrangements for sharing the benefits of the use of the resources and/or knowledge are generally binding through contractual arrangements, declarations or registration systems. transactional nature of this approach links access and benefits to the provider of the resources.

The Plant Treaty and PIP Framework are examples of a multilateral approach to ABS. The Plant Treaty applies to a negotiated selection of plant genetic resources used for food and agriculture (Articles 11.1, 15.1 and 15.5). The PIP Framework applies to the sharing of H5N1 and other influenza viruses with human pandemic potential (Article 3). The multilateral approach requires Plant Treaty Contracting Parties and WHO Members for the two frameworks, respectively, to provide access to resources and information, subject to benefit sharing arrangements such as technology transfer and capacity building. Unlike the bilateral approach where the country provider has control over access and is the recipient of benefits that flow from their use, under the multilateral approach, once materials have been entered into the system, the benefits flow to the collective to achieve a particular goal (e.g. food or health security).

Most of these policy-based articles were focused at the global level (383 articles), discussing the potential impacts, benefits, challenges and administration related to implementing global or regional-level ABS policy. Similar patterns were found at the regional level with increased focus on the impacts of global policy on local communities, traditional knowledge, food security, national legislation and enforcement.

Despite the importance of (and prevalence of articles on) international policy, conventions or treaties regulating ABS of genetic resources, only 86 articles (11.4%) focused on the national legislation required to meet these international obligations. In many cases, articles discussed the lack of—and critical need for—appropriate national ABS legislation, particularly in Africa and Asia. This lack of national ABS legislation was linked to misappropriation of traditional knowledge, bioprospecting and biopiracy. Enforcement remains a key issue for many countries. 14

3.2.1.1. Africa: International or regional policies, conventions and treaties were the focus of more than 65% of all the African articles. These included the CBD, Nagoya Protocol, Plant Treaty, the 2001 African Model Law on the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources (African Model Law) and the African Union Strategic Guidelines [and Practical Guidelines] for the Coordinated Implementation of the Nagoya Protocol in Africa (AU Guidelines). African

countries have used the African Model Law as a guide to implement their national ABS laws and continues to be used as a template to guide approaches towards Farmers' Rights (see traditional knowledge section below). The African Union Assembly adopted the AU Guidelines in 2015 to provide up to date practical guidance to Member States 'on how national ABS systems can be implemented in a regionally coordinated manner, consistent with the provisions of the Nagoya Protocol, so as to preserve key African interests and positions'. <sup>15</sup>

Many articles were based at the regional level discussing the ABS policies currently existing or proposed for the region, the outcomes of these policies at the regional and national level, the organisations responsible for implementing ABS and challenges related to policy implementation at the regional scale. 16 More specific examples of African regional policy issues include: (i) the centralization of power with federal governments; (ii) generality or vagueness of policies; (iii) lack of regulations guidelines and for effective implementation of policy; (iv) poor drafting of ABS agreements; and (v) the wide discrepancy between nations in terms of ABS policy implementation and capacity.

At the national level, there was increased focus on the impacts of regional policy on intellectual property, traditional knowledge, bioprospecting, local community awareness, national legislation and enforcement. Issues relating to bioprospecting, intellectual property and national legislation were particularly prevalent in South Africa.<sup>17</sup> In many cases, questions were raised regarding:

- (1) which institutions were involved in and responsible for ABS activities at the national level?
- (2) what were the national-level administrative arrangements for ABS management?
- (3) who was responsible for enforcing national or regional ABS regulations?
- (4) who were the major ABS stakeholders?
- (5) what ABS-related projects or activities were being conducted in each country? and
- (6) what actions are needed to clarify, develop and implement ABS measures in each country?

3.2.1.2. Asia: International or regional policies, conventions and treaties were the focus of more than

70% of all the articles about Asia and Asian countries. These included the CBD, Nagoya Protocol and the Plant Treaty. In 2000 the Association of Southeast Asian Nations (ASEAN), which represents ten South East Asian countries, produced a regional ABS protocol among members – the ASEAN Framework Agreement on Access to Biological and Genetic Resources. The objectives of the Framework Agreement include:

- To promote cooperation among ASEAN
   Member States in the utilization of, and
   providing access to biological and genetic
   resources and encourage the sharing of
   resources:
- To ensure that access regulations within the ASEAN region are uniform and consistent in accordance with identified minimum requirements as set out in this Framework Agreement;
- To set minimum standards in regulating access to biological and genetic resources and to strengthen national initiatives towards this objective; and
- To promote technology transfer and capacity building at the regional, national and community levels (Article 2).

Almost all articles were focused at the national level examining the impacts of policy on intellectual property, traditional knowledge, and national legislation. Most of these articles focused on India, Malaysia, Indonesia, China and the Philippines with little published about the rest of the region.

3.2.1.3. Europe: International or regional policies, conventions and treaties were the focus of more than 85% of all the European articles. These included the CBD, Nagoya Protocol, Plant Treaty, and EU Regulations relating to ABS. The EU's regulations bind member States and users of genetic resources and associated traditional knowledge in the EU, whether or not they are individually parties to the NP.<sup>19</sup> These regulations include *Regulation (EU)* No.511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union. This provides a due diligence framework for ensuring that anyone conducting research and development in the EU demonstrates that the genetic resources and/or traditional knowledge are accessed and used in accordance with the legislation of the providing country. Other supporting instruments include the Commission *Implementing* Regulation 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitor user compliance and best practices and the Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagova Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union European Commission.

Member States are free to decide whether they control access, which is not covered by the EU Regulations. At the time of writing only Bulgaria, Croatia, France, Malta, Spain, the Walloon Region in Belgium and the Autonomous Region of Azores in Portugal have implemented ABS rules for their genetic resources and traditional knowledge, while Finland and Denmark have ABS laws for their traditional knowledge only.

Most articles were based at the regional level discussing the ABS policies currently existing or proposed for the region, the outcomes of these policies at the regional and national level, the organisations responsible for implementing ABS and challenges related to policy implementation at the regional scale.<sup>20</sup> More specific examples of European regional policy issues include:

- (1) the definition and inclusion of traditional knowledge;
- (2) different regulations for access to European genetic resources;
- (3) the lack of ABS regulations by European user countries leading to stricter ABS requirements in provider countries which impact on a wide range of European economic and environmental stakeholders;
- (4) poor regional and national level compliance measures; and
- (5) strong horizontal division of competences among many different relevant administrative sectors, which do not necessarily coincide across countries.

3.2.1.4. North America: International or regional policies, conventions and treaties were the focus of more than 60% of all the North American articles. These included the CBD, Nagoya Protocol and the Plant Treaty. Most articles were based at the national level discussing the ABS policies currently existing or proposed, the outcomes of these policies at the national level, the organisations responsible for implementing ABS and research and development implications of these policies.<sup>21</sup> Policy was the key discussion point in articles from the United States (11, 61%) but not Canada (4, 44%).

3.2.1.5. Oceania: International or regional policies, conventions and treaties were the focus of more than 60% of all the Oceania articles. These included the CBD, Nagoya Protocol, UN Convention on the Law of the Sea (UNCLOS), Plant Treaty, and the Melanesian Spearhead Group Framework Treaty on the Protection of Traditional Knowledge and Expression of Culture, which concerns regulation of access to traditional knowledge and equitable benefit sharing.

Most articles for Oceania were based at the national level discussing the ABS policies currently existing or proposed, the outcomes of these policies at the national level, the organisations responsible for implementing ABS and challenges related to policy implementation at the national scale.<sup>22</sup> Unlike other regions (e.g. Africa), there was much less published on regional approaches, issues and challenges with ABS in Oceania.<sup>23</sup> This is most likely due to the vast disparity between the capacities of the different countries in the region to develop, implement and enforce ABS polices, regulations and treaties. There was a large variation in publications on ABS in Australia compared to the other Oceania nations.

At the national level there was increased focus on the impacts of policy on intellectual property, traditional knowledge, national legislation and governance in Australia<sup>24</sup> and biological control and conservation in New Zealand.<sup>25</sup> In the rest of the region, ABS policy focus was on traditional knowledge, customary law and marine aquatic resources.<sup>26</sup>

3.2.1.6. South America: International or regional policies, conventions and treaties were the focus of almost 50% of all South American articles. These included the CBD, Nagoya Protocol, Plant Treaty,

and the 1996 Decision 391 – Common Regime on Access to Genetic Resources (Andean Pact Decision 391). Andean countries including Bolivia, Colombia, Ecuador, Peru and Venezuela were the first to take a regional approach to ABS cooperation and measures.

A good summary of the implementation of the Nagoya Protocol in the region is provided in The Implementation of the Nagoya Protocol in Latin America and the Caribbean: Challenges and Opportunities, 27 focusing on Andean and Central American countries. While published nine years ago, it remains relevant for its examination of the interface between the Nagoya Protocol and the national ABS laws and related policies in the region. Overall, Cabrera Medaglia highlighted the high level of legislative action in the region on ABS issues, with some countries having put in place several ABS measures such as Peru, Brazil and Venezuela. including specific legislation traditional knowledge issues. The region has also been a pioneer both in the development of legal frameworks on ABS (e.g. Andean Community, Costa Rica and Brazil) and associated traditional knowledge (e.g. Peru and Panama).

The level of implementation of these ABS measures, however, was low due to several challenges such as: (i) defining ownership of genetic resources; (ii) difficulties in controlling access to genetic resources; (iii) high transaction costs associated with the permitting processes; (iv) the lack of certainty created by the different frameworks; and (v) the lack of capacity to negotiate ABS agreements.<sup>28</sup> Several of these challenges were also identified by other publications.<sup>29</sup> Filoche (2013) highlighted the issues associated with some countries changing their status from provider to user countries of genetic resources.<sup>30</sup> More recently, Muzaka and Serrano (2019) provide a comprehensive overview of the issue of benefit sharing from genetic resource use in Brazil including a detailed description of the increasing significance of Brazil on the global stage in relation to genetic resource use and exchange policy and practice, intellectual property and benefit-sharing regimes.<sup>31</sup>

## 3.2.2. Theme 2: Intellectual Property

More than a third of the global library articles (37%) dealt with aspects of intellectual property and ABS of genetic resources. At the international level, the treaty of most relevance to ABS is the World

Trade Organization's (WTO) Agreement Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS establishes minimum standards of protection for a range of intellectual property including patents and copyright for WTO Members. Intellectual property may ownership and control of physical genetic resources, associated information (such as digital sequence information) and traditional knowledge associated with genetic resources. The CBD and Nagoya Protocol do not affect intellectual property but do encourage countries to cooperate to ensure that such rights under national legislation are supportive of and do not run counter to the objectives of the CBD (Article 16(5)) and Nagoya Protocol (Article 4).

There have been significant debates international forums about whether there should be a mandatory requirement for patent applicants to disclose the origin of the genetic material and/or traditional knowledge used in an invention. This may provide a means of tracing their use back to the original provider for a fair and equitable share of the benefits from their use. Such forums include the WTO, where a group of provider countries have been seeking an amendment to TRIPS,<sup>32</sup> UN World Intellectual Property Organisation's (WIPO) Intergovernmental Committee on Intellectual Property, Genetic Resources. Traditional Knowledge and Folklore the UN's and Intergovernmental Conference for an Implementing Agreement under the UN Convention on the Law of the Sea for the Conservation and Sustainable use of Marine Biodiversity.33 Despite lack of progress at the international level, an increasing number of countries require disclosure of origin of genetic resources under national patent or ABS legislation, such as India, Malaysia, Viet Nam and Zambia.

At the national level, intellectual property is usually a separate body or system of laws to ABS, although some countries' laws intersect in various ways. For example, some countries such as India, Bangladesh and Uganda require government permission under their ABS laws before seeking intellectual property protection concerning their genetic resources and/or traditional knowledge. Several countries such as the Philippines, Viet Nam and Zambia include intellectual property as a form of benefit sharing (such as a share of royalties). Some national legislation such as Malawi and India requires the public disclosure of information, which may affect patent applications. A small number of countries such as Kenya and Uganda protect

traditional knowledge as a *sui generis* intellectual property system under their national legislation.

In the literature, intellectual property was generally discussed in relation to traditional knowledge, bioprospecting, biopiracy, policy and national level legislation.<sup>34</sup> This topic was particularly prevalent in North America (44.8%), South America (48.6%), Africa (37.4%) and at the global level (37.5%) (Table 1). Articles from North America were divided between those focusing primarily on intellectual property in relation to patents and enforcement of national intellectual property legislation in the United States<sup>35</sup> and those related to traditional knowledge in Canada.<sup>36</sup> In South America articles primarily dealt with issues of intellectual property in relation to the patenting of traditional knowledge (usually plants) bioprospecting.<sup>37</sup> Articles about Africa were divided into those focused on intellectual property in relation to traditional knowledge, bioprospecting and biopiracy<sup>38</sup> and those related to national intellectual property legislation and enforcement.<sup>39</sup> Similar patterns were found in Asia-focused articles. 40 Most articles discussed intellectual property without specific reference to taxonomy of the genetic resources (133, 46.8%). The majority of taxa-specific articles focused on intellectual property in relation to plant genetic resources (101, 35.6%), particularly crop plant varieties and plants used in traditional medicines.<sup>41</sup> Only 15 articles examined intellectual property specifically in relation to animal genetic resources, including seven on aquaculture species.<sup>42</sup>

3.2.2.1. Africa: In recent years, African countries have participated to an unprecedented degree in both international and bilateral initiatives dealing with intellectual property.<sup>43</sup> More than a third of all articles about Africa (34, 37.4%) dealt with aspects of intellectual property and ABS of genetic resources. Given the increasing commodification and commercialisation of indigenous cultural and intellectual property in Africa,44 intellectual property was generally discussed in relation to traditional knowledge (70% articles) and policy (71%). These included Nagoya Protocol, TRIPS, the 1977 Agreement Relating to the Creation of an African Intellectual Property Organization (Bangui Agreement) and the Swakopmund Protocol on the Traditional Protection of Knowledge Expressions of Folklore within the Framework of the African Regional Intellectual Property Organization

(Swakopmund Protocol). The latter Protocol was adopted by the Diplomatic Conference of the African Regional Intellectual Property Organization on 9 August 2010 and its purpose is to 'protect traditional knowledge holders against any infringement of their rights' and 'protect expressions of folklore against misappropriation, misuse and unlawful exploitation beyond their traditional context' (section 1).

Roughly half of the articles discussed intellectual property without specific reference to taxonomy of the genetic resources (16, 48%). Most taxa-specific articles focused on intellectual property in relation to plant genetic resources (16, 48%), particularly plants used in traditional medicines and crop plant varieties.<sup>45</sup> Only one article examined intellectual property in relation to animal genetic resources. African regional intellectual property initiatives have been developed as a strategy to improve access to foreign technology and increase regional negotiation capacity and competitiveness but are often hindered by the different intellectual property regimes in different countries, varied levels of national legislation development and enforcement. These regional intellectual property regimes and African Organization organisations, e.g. Intellectual Property (OAPI), are also often criticised for not including and addressing the concerns of rural communities.<sup>46</sup>

3.2.2.2. Asia: Almost half (52, 46%) of the articles about Asia dealt with aspects of intellectual property and ABS of genetic resources. Intellectual property was generally discussed in relation to policy (69% articles), traditional knowledge (45%) and national legislation (35%). Several countries are members of the ASEAN and committed to complying with the ASEAN Framework Agreement on Intellectual Property Cooperation of 1995, and subsequent action plans including the ASEAN Intellectual **Property** Rights Action Plan 2004–2010, the Work Plan for Cooperation on Copyrights, the ASEAN Intellectual Property Rights Action Plan 2011-2015, and the newly updated ASEAN Intellectual Property Rights Action Plan 2016–2025. More than 60% of articles discussed intellectual property without specific reference to taxonomy of the genetic resources (32, 63%). Most taxa-specific articles focused on intellectual property in relation to plant genetic resources (19, 37%), particularly plants used in the pharmaceutical industry and crop plant varieties.<sup>47</sup>

Only two articles examined intellectual property in relation to animal genetic resources, both related to aquaculture genetic resources.<sup>48</sup>

3.2.2.3. Europe: The few articles (7, 12.3%) examining intellectual property and ABS of genetic resources focused primarily on the 'disclosure of origin' requirements in patent applications<sup>49</sup> and the implementation of EU ABS regulations by European nations.<sup>50</sup> Rosendal et al. (2013) examine ABS and legal protection of breeding innovations in Norwegian aquaculture highlighting how corporate strategies, technological developments, and international regulatory regimes influence access to genetic material and intellectual property.<sup>51</sup>

3.2.2.4. North America: Almost half of all articles (45%) dealt with aspects of intellectual property and ABS of genetic resources. Intellectual property was generally discussed in relation to policy and national level legislation, research and traditional knowledge<sup>52</sup> and almost exclusively in relation to plants. Articles from North America were divided between those focusing primarily on intellectual property in relation to patents and enforcement of national intellectual property legislation in the United States<sup>53</sup> and those related to traditional knowledge in Canada.<sup>54</sup>

3.2.2.5. Oceania: More than a third of all Oceania articles (15, 34.9%) dealt with aspects of intellectual property and ABS of genetic resources, most of these focused on Australia (8, 62%) or Fiji (3, 23%). Outside of Australia and New Zealand there is little exploration in the literature of intellectual and cultural property rights.<sup>55</sup> Intellectual property was generally discussed in relation to traditional knowledge (61% articles) and policy (46%), e.g. Nagoya Protocol, TRIPS. The articles discussed intellectual property in relation to plants (7, 54%) or did not specify the taxonomy of the genetic resources (6, 46%). Most plant-specific articles focused on intellectual property in relation to bush tucker, traditional medicines and crop plant varieties.<sup>56</sup> No articles examined intellectual property in relation to animal genetic resources.

3.2.2.6. South America: Intellectual property rights in relation to ABS of genetic resources were the focus of almost 50% (17 articles) of the South American articles. Intellectual property was generally discussed in relation to policy (71% articles), traditional knowledge (47%) and bioprospecting (24%). More than 70% (12) of

articles discussed intellectual property without specific reference to taxonomy of the genetic resources. Most taxa-specific articles focused on intellectual property in relation to plant genetic resources (5, 29%), particularly plants used in the pharmaceutical industry and crop plant varieties.<sup>57</sup> Only one article examined intellectual property in relation to animal genetic resources,<sup>58</sup> while there were no articles focused on microbial or fungal genetic resources in the region.

# 3.2.3. Theme 3: Traditional Knowledge

Traditional knowledge was the focus of 32% (240) of global library articles, particularly in relation to intellectual property, bioprospecting, and national legislation. The CBD and Nagoya Protocol ask Contracting Parties, in accordance with their domestic laws, to ensure traditional knowledge held by Indigenous Peoples and local communities (IPLCs) is accessed with the prior and informed consent or approval and involvement of IPLCs and mutually agreed terms and that the benefits arising from the use of such knowledge is shared in a fair and equitable way with the knowledge holders (CBD Article 8(i), NP Articles 5 and 7). The CBD's obligations are potentially broader in scope where the knowledge relates to biological diversity at each of the ecosystem, species and genetic levels.<sup>59</sup> The Nagoya Protocol's obligations are confined to 'traditional knowledge associated with genetic resources' (Article 7). Other forums also deal with traditional knowledge either in the context of ABS, such as the Plant Treaty, which is confined to 'traditional knowledge relevant to plant genetic resources for food and agriculture' (Article 9.2(a)), or more broadly. These broader discussions (which are also generally relevant to ABS) are in relation to the World Trade Organisation's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), the UN Declaration on the Rights of Indigenous Peoples (UNDRIP), the UN Educational, Scientific and Cultural Organization (UNESCO) WIPO's agreements, and Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. It is up to each country to decide the meaning and scope of traditional knowledge within their jurisdiction.

Several ABS articles relating to traditional knowledge, particularly in the context of Africa and Asia, explore the knowledge systems in the context of Farmer's Rights and to a lesser extent, Livestock

Keepers' Rights. The Plant Treaty provides for traditional knowledge as an element of Farmers' Rights. In careful diplomatic text the obligation is a 'responsibility for realizing Farmers' Rights... [i]n accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including: (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture' (Article 9.2). Plant Treaty obligations (including ABS) must not be interpreted as limiting the activities of saving, using, exchanging and selling farm-saved seeds and propagating materials, subject to national law (Article 9.3). Livestock Keeper's Rights emerged as a concept propounded by civil society groups during discussions leading to the *Interlaken* Declaration on Animal Genetic Resources as an allusion to Farmers' Rights in the Plant Treaty.<sup>60</sup> These are 'a bundle of rights that includes rights to grazing, water, markets, training and capacity building, and participation in research design and policy-making, as well as rights to the genetic resources of their animals'. 61 More recently, the issues of Livestock Keeper's Rights have been addressed though the Global Plan of Action for Animal Genetic Resources and the CBD's subsidiary bodies, such as the Ad hoc Working Group on Article 8(j) and Related Provisions.<sup>62</sup>

The focus on traditional knowledge in the ABS literature was much higher in biodiverse regions with high levels of local community use of natural resources (e.g. Africa 51%, Oceania 51%, South America 41%). Thirty-eight per cent of articles from North America focused on traditional knowledge. Very few articles focused on traditional knowledge in Europe (4, 7%). Most traditional knowledge articles were non-taxa specific (163, 68%), the remainder were focused on plants (77, 32%), primarily species involved in traditional medicine or farmer varieties. 63 No traditional knowledge articles were specifically related to animal or microbial genetic resources. Articles on traditional knowledge and national legislation were generally focused on the importance of national ABS legislation in relation to traditional knowledge of genetic resources, the lack of this legislation in most countries and/or theinability of most countries to enforce the legislation.<sup>64</sup>

*3.2.3.1.* Africa: Half the articles about Africa (46, 50.6%) dealt with aspects of traditional knowledge,

generally focusing on intellectual property, bioprospecting, and national legislation. Issues relating to traditional knowledge were found region-wide reflecting the importance of local culture, traditional knowledge and customary use of biodiversity and genetic resources within Africa. African plant biodiversity and endemicity is high and many articles focused on the traditional knowledge associated with plant species. medicines.65 particularly traditional Other plant-related traditional knowledge articles examined ABS in relation to farmer knowledge and local crop diversity.<sup>66</sup> Articles on traditional knowledge and national legislation were either focused on genetic resources in general or a group of well-known case studies, e.g. Hoodia gordonii and the San people in Botswana, South Africa and Namibia.67

3.2.3.2. Asia: Almost 40% of articles about Asia (45 articles) dealt with aspects of traditional knowledge, generally focusing on policy, intellectual property, and national legislation. Issues relating to traditional knowledge were reported from all countries reflecting the importance of local culture, traditional knowledge and customary use of biodiversity and genetic resources within Asia, including Farmers' Rights. Ramanna (2003) and Kanniah (2005) examine intellectual property policies in agriculture where the major issues include: (i) the impacts of intellectual property on the price of seeds; (ii) the rise of bio-piracy; (iii) access of farmers to seeds; and (iv) the impact of property rights on biodiversity.<sup>68</sup> As members of the WTO. Asian countries are required to extend intellectual property protection in agriculture in accordance with TRIPS obligations. Domestically, however, there is strong demand for granting Farmers' Rights and ensuring that intellectual property does not threaten food Consequently, various countries in Asia have or are currently attempting to develop a twin strategy of granting both plant breeders' rights (a form of intellectual property for plant varieties) with Farmers' Rights. Balakrishna (2001) examines the link between the CBD, intellectual property and voluntary codes of conduct to facilitate ABS in Asia.<sup>69</sup> More recently, Kamardeen (2015) examines community rights to intellectual property in Asia, particularly community access to pharmaceutical and agro-chemical innovations that are protected by intellectual property regimes.<sup>70</sup>

Many articles focused on the traditional knowledge associated with plant species, particularly traditional medicines used in the pharmaceutical industry<sup>71</sup> and crop varieties.<sup>72</sup> Articles on traditional knowledge and national legislation were only based in India, the Philippines and Malaysia.

3.2.3.3. Europe: Unlike other regions where traditional knowledge is a key component of ABS (see Table 2 for comparisons), only four articles (7%) dealt with aspects of traditional knowledge in Europe. This is likely due to the different definitions and inclusions of traditional knowledge in national policy, including consideration that traditional communities may no longer exist in some countries,<sup>73</sup> and the fact that European countries are generally users rather than providers of genetic resources.

*3.2.3.4. North America:* Thirty-eight per cent of articles about North America focused on traditional knowledge but this was primarily due to the importance of traditional knowledge in Canada (90% of Canadian articles)<sup>74</sup> rather than the United States (17%).<sup>75</sup> The Canadian articles discussed ABS of genetic resources in relation to plants used for traditional medicine,<sup>76</sup> food<sup>77</sup> and the importance of the protection of traditional knowledge itself.<sup>78</sup>

3.2.3.5. Oceania: Over half (22, 51.2%) of the Oceania articles dealt with aspects of traditional knowledge, generally focusing on intellectual property, bioprospecting, and national legislation. Local culture, traditional knowledge and customary use of biodiversity and genetic resources are critical issues in Oceania given that many of the land, sea and natural resources in Islander countries are traditionally owned. Half of the traditional knowledge related articles focused on plant species, particularly 'bush tucker' in Australia<sup>79</sup> and traditional medicinal species.<sup>80</sup> Other plant-related traditional knowledge articles examined ABS in relation to forest conservation and biopiracy.<sup>81</sup> Articles on traditional knowledge and national legislation were almost exclusively from Australia.

3.2.3.6. South America: Safeguarding or protecting the interests of indigenous and local

communities over their knowledge and practices has often been one of the objectives of ABS legislation in the South America. It is reflected in the Andean Community common regime, as well as in domestic ABS regimes in Peru, Colombia and Brazil, to recognise and protect the rights of indigenous peoples to make decisions about their innovations, practices and knowledge associated with genetic resources. As a result, forty percent of South American articles dealt with aspects of traditional knowledge, generally focusing on intellectual property, bioprospecting and national legislation. All the articles focused on traditional knowledge associated with plant species involved traditional medicines and/or crop species.<sup>82</sup> In some countries, specific legislation, in addition to the broader ABS measures, exists to guarantee the right of indigenous peoples over their traditional knowledge or genetic resources located in their lands (e.g. Venezuela, Panama, Peru, Ecuador, Bolivia, Colombia).83 Given the geospatial complexity in traditional knowledge patterns within the region, however, Cámara-Leret et al. (2014) underscore the need for improved insight into the ownership of traditional knowledge in areas where biocultural diversity is high and traditional knowledge associated with one species encompasses multiple nations and cultural groups.84

# 3.2.4. Theme 4: Research, Development and Commercialisation

This key topic encompasses commercial research (classified as 'bioprospecting'), non-commercial research and biobanks. The CBD's ABS framework applies to research and development concerning genetic resources and benefits arising from the commercial and other utilization of genetic resources (Article 15(7)). The Nagoya Protocol introduced new definitions for 'utilization of genetic resources' and 'derivatives', which clarify the activities and subject matter that fall within the scope of its ABS obligations:

• 'Utilization of genetic resources' means 'to conduct research and development on the genetic and/or biochemical composition of genetic resources, including though the application of biotechnology [meaning "any technological application that uses... derivatives [of living organisms] to make or modify products or processes for specific use" (CBD Article 2)]'

• 'Derivative' means 'a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity' (NP Article 2).

In developing and implementing ABS legislation, Parties to the Nagoya Protocol are required to create conditions to promote and encourage research, which contributes to the conservation and sustainable use of biodiversity, including through simplified measures on access for non-commercial research purposes (Article 8(a)).

The issue of ABS of genetic resources in relation to non-commercial (e.g. research) uses was only covered in 57 (7.5%) of all articles. Most articles on this topic concerned exchange of genetic material for research at the global level (34, 59.6%) or within Europe (11, 19.3%). This issue was often linked with biobanking, particularly seed banks, of important crop species to improve food security in the face of global climate change. Several articles discussed how international policy (e.g. the Nagoya Protocol) would impact on the administrative load and paperwork (e.g. Material Transfer Agreements) associated with genetic resource transactions for research purposes, essentially stifling research growth and development in a number of fields.

The issue of bioprospecting and ABS of genetic resources was examined in 112 articles (15%), primarily in relation to the pharmaceutical industry.<sup>87</sup> There is currently no internationally agreed-upon definition of the term 'bioprospecting'. However, a note prepared by the CBD Secretariat defined bioprospecting as 'the exploration of biodiversity for commercially valuable genetic and biochemical resources'. 88 Bioprospecting as a topic was more prevalent in biodiverse region articles (Africa 16.5%, Asia 12%, Oceania 16.3%, South America 18.8%) than Europe (8.8%) and North America (3.4%). Most taxa-specific articles related to bioprospecting of plants or marine species.<sup>89</sup> Biopiracy was a related issue in some articles particularly those focusing on national legislation to ensure fair and equitable benefits for local resource owning communities and countries.

3.2.4.1. Africa: The issue of bioprospecting and ABS of genetic resources was examined in 15 articles (16.5%), primarily in relation to the pharmaceutical industry. Biopiracy was a related issue in some articles. Some articles focused on

bioprospecting in general, however, several were based on specific well-known case studies. For example, bioprospecting in relation to the harvesting, trade, and commercial development of Hoodia. This case study highlights the issues involved with bioprospecting and natural product development of a species that crosses national borders and involves several distinct indigenous communities.90 Although each of the three countries where Hoodia naturally occurs have regulatory approaches, distinct different understandings of the role of traditional knowledge and different approaches to the plant's conservation and use, they have increasingly collaborated to design joint policies to better manage and prevent poaching, trade and the transport of illegally harvested material.91

3.2.4.2. Asia: Research, development and commercialisation of genetic resources was examined in 17 (15%) of ABS articles, primarily in relation to plant and marine genetic resources the pharmaceutical and biotechnology industries. 92 The articles examining bioprospecting of genetic resources in Asia were generally concerned with inequity in benefit sharing and/or the use of knowledge.93 From traditional research perspective, Nijar et al. (2017) discusses the practical challenges in operationalizing ABS measures stemming from adoption of the Nagoya Protocol such as minimum access standards, mandatory prior informed consent of indigenous communities, compliance with domestic laws or requirements of the provider country monitoring the utilization of genetic resources for non-commercial research.94

3.2.4.3. Europe: Research and non-commercial use of genetic resources was the focus of 11 (19.3%) articles. Many of these focused on plant or microbial genetic resources 95 and the impacts of ABS regimes on access to and use of these resources for research purposes, including the need for appropriate mutually agreed terms. Given that European countries are primarily the users rather than providers of genetic resources, limited European ABS regulations may lead to restrictive ABS policy in provider countries. This may subsequently affect a range of research-focused or non-commercial users such as botanic gardens, culture collections, gene banks, and academic research institutions. 96

3.2.4.4. North America: Research and development or non-commercial use of genetic resources was the focus of three (10.3%) articles in North America. These articles discussed the challenges and implications of several international treaties and polices on access to and sharing of genetic resources for the United States, even if the United States itself was not a signatory. Given that the United States is primarily a 'user' of genetic resources, being a non-signatory does not divest it of its obligations under national legislation of 'provider' countries.

3.2.4.5. Oceania: The issue of bioprospecting and ABS of genetic resources was examined in seven articles (16%) mainly in relation to marine bioprospecting. The issue of bioprospecting regulation in Oceania moves between the extremes of multi-jurisdictional regulation (as seen in Australia) to the absence of any national regulation in most other nations. This pattern is reflected in most other national-level legislation relating to ABS in Oceania – with Australia having laws on ABS, intellectual property, biodiscovery, and conservation at the Commonwealth and State level while the majority of the other nations currently do not have national-level legislation in many of these areas.

3.2.4.6. South America: The of bioprospecting and ABS of genetic resources was examined in six articles (18.8%), primarily in relation to the pharmaceutical industry. Biopiracy was a related issue in some articles – particularly those focusing on national legislation to ensure fair and equitable benefits for local resource owning communities. For example, bioprospecting and biopiracy in relation to the harvesting, trade, and commercial development of Quassia amara in French Guiana for malaria treatment 100 and epibatidine from poison dart frogs in Ecuador for analgesics. 101 These case studies highlight the debates and legal issues involved bioprospecting and natural product development of species covered by different legal frameworks and determining whether traditional knowledge has been used (with or without consent).

# 4. Discussion

The purpose of a SQLR is to summarise the status of the literature so that the results are reliable.

quantifiable and reproducible. The SQLR highlights knowledge gaps and identify where research may be needed to address the gaps. This SQLR of the ABS literature about genetic resources, associated information and associated traditional knowledge reveals a vibrant literature about ABS with the global library containing 757 articles. The following summarises the key gaps:

- Geographic patterns in ABS Across the regions of Asia, Africa, Europe, North America, South America and Oceania, ABS has been addressed, although unevenly and with much of the ABS literature focussed in a few specific countries from these regions: India, South Africa, Norway, USA, Brazil and Australia respectively (Table 1). The major gaps in the literature were about ABS schemes at the national level. This was particularly apparent in the literature about developing countries, most of which were not addressed at all in any literature beyond a regional level engagement.
- 2) ABS policy and law International ABS policy, conventions or treaties are well covered by the literature, while, again, literature focused on the national legislation required to meet these international obligations was limited. A further gap was in the comparative approaches to implementing international ABS obligations to assess the different ways ABS might be developed, implemented and enforced, including administrative, policy and formal legislative approaches.
- 3) Intellectual Property Intellectual property remains a vexed issue in the ABS literature as it predominantly involves areas of policy and law that are not specifically about ABS but rather how these policies and laws interact with ABS policy and law. While there are ongoing debates about patent disclosures, traditional knowledge, bioprospecting, biopiracy, and so on, there remain gaps in other ways of valorising genetic resources that might promote the objectives of both intellectual property and ABS (different mechanisms for benefit sharing). There also remains a gap in addressing the apparent conflict between challenging exclusivity for intellectual property like patents and plant breeder's rights while promoting exclusivity for traditional knowledge claims.
- 4) Traditional knowledge While there is a considerable focus on traditional knowledge in the ABS literature, this attention is presently mostly speculation about the potential protections for traditional knowledge because the issues are being slowly addressed through a range of forums, such as WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The gaps in the literature are not about whether traditional knowledge should be protected, but rather how that might be achieved generally and how this might be achieved as part of the ABS arrangements. The key gaps in the present literature are about the form and content of protocols agreed by traditional knowledge holders on what they consider is ABS-relevant traditional knowledge and how that might be addressed, particularly for the traditional knowledge of local communities. In this respect, traditional knowledge relevant to ABS tends to be part of larger debates about self-determination, respect, and so on, as detailed in the UN Declaration on the Rights of Indigenous Peoples (UNDRIP), and similar agreements. The traditional knowledge of local communities (in contrast to Indigenous Peoples) is almost never addressed.
- 5) Research, development and commercialisation - The distinction between commercial and non-commercial research in ABS polices and laws remains contested because the benefit sharing aspect of ABS depends on a commercial outcome, and non-commercial research is undoubtedly leading to some form of commercialisation at some point in the future. A key gap in the literature remains in finding a resolution to an acceptable demarcation between commercial and non-commercial research, the former attracting the transaction costs of ABS while the latter avoiding some of that administrative complexity in some countries. A further gap is the lack of best practice examples where the outcomes of ABS have led to successful commercialisation and quantifiable benefit sharing (both monetary and non-monetary). This is particularly important as ABS may be delivering many non-monetary benefits that may be difficult to quantify and may not be captured by those providing access.

There was a strong focus in the literature on ABS policy and law (80% of articles) including implementation, obligations and challenges. There was a dearth of articles about ABS at the regional or national level, particularly for developing nations with high levels of biodiversity, limited ABS legislation and enforcement and poor protection of their national genetic resources. Future literature is likely to address how to enforce policies and laws at the regional or national levels, and how to manage the issue of countries that are not signatories to the various international treaties, regulations and policies (like the United States) and countries that do not have clear ABS policies and laws despite having CBD and Nagoya Protocol obligations. As this SQLR shows, only 77 countries were addressed leaving 119 countries that are parties to the CBD unaddressed, and this is primarily because these countries have no ABS policies and laws. These countries pose a significant burden on the effectiveness of ABS arrangements because the ABS arrangements assume that genetic resources (and derivatives) can be traced to a country of origin for appropriate benefit sharing and for lawful future utilisation, and to address the concerns about biopiracy. A further problem will be addressing genetic resources where there is no account for their provenance or origin (Nagoya Protocol. Preamble).<sup>102</sup> Given relatively the implementation of national ABS policy in many countries, there is also a critical need for research on impacts of policy and law implementation at the regional, national and community (local) level, contract/report/tracking including permit/ obligations for local communities, penalties for infringement, the need for detailed mutually agreed terms and prior informed consent, and overlap or conflict between different policies and laws, such as intellectual property.

A related issue is about compliance with ABS policies and laws. While there is designated ABS legislation in several countries and regions, current compliance mechanisms appear to be weak spots in the literature and in practice. Despite this poor national level compliance, however, several semi-public or private ex situ collections and organisations have established self-regulated compliance measures in line with international policy and law, e.g. Belgian Coordinated Collection of Microorganisms (BCCM) and International Plant Exchange Network (IPEN). These organisations utilise standardized contractual clauses

procedures for collecting, accessing and exchanging genetic resources, which are compliant with the provisions of the Nagoya Protocol. More research on the effectiveness of these practices is needed for other similar collections globally. Future research might be expected to address these alterative mechanisms and perhaps posit guidance and implementation materials to facilitate their adoption by countries and regions without the capacity to enforce compliance.

There was a very strong overall bias towards plants (32% of articles), due to the relatively advanced standing of the plant-based agricultural and pharmaceutical sectors and the existence of plant-specific ABS-related policies and regulations. Publications on animal (5%), microbial (2%), and fungal (0.1%) genetic resources form a very small component of the overall ABS literature. There was a similar strong bias in information on intellectual property related to plant genetic material (35% of articles) - especially pharmaceutical species and crop varieties. These biases may simply reflect the relative roles of plant, animals, microbes and fungi in ABS arrangements, or might point to a more significant concern that ABS as presently formulated does not function for those non-plant kinds of genetic resources. This is concerning as ABS is now intimately tied to the Sustainable Development Goals and the potential that only utilising (or using) plants as contributing towards those goals means that the assumed contributions of non-plants will undermine the Sustainable Development Goals' achievements. More research is required to understand why animals, microbes and fungi are not addressed more in the literature and whether this is a symptom of a more significant policy and law issue for ABS.

There was a strong emphasis on ABS of genetic resources for commercial uses, with only 53 (7.4%) articles focused on the need for ABS in relation to non-commercial use of genetic resources for research, biodiversity conservation, food security or climate adaptation. As set out above, the distinction between commercial and other uses remains contested and there is a gap in the case studies about benefit sharing following ABS implementation. Although. some recent examples demonstrate that ABS itself is only a part of a broader policy and law landscape necessary to both deal with ABS and the harness the potential for benefits. The recent Rooibos Benefit Sharing Agreement in South Africa shows the dimensions of a more sophisticated policy and law landscape to enable right holders to negotiate and the capacity of representative groupings to negotiate on behalf of users and their end users. <sup>103</sup> More research is required to detail these more complex landscapes to properly understand the dimensions of necessary policy and law to enable and deliver ABS.

Another area that is evolving rapidly and might be expected to be addressed in future literature is traditional knowledge. Many 'user' countries, e.g. the United States, do not explicitly address the issue of traditional knowledge in relation to genetic resources. Given the primary 'user' role of these nations, stricter ABS policies and laws of provider countries that include traditional knowledge, will have large impacts on their access to and use of genetic resources. How these provider country provisions will reach through to 'user' countries are presently poorly addressed in the literature. More research will be required to understand the content of traditional knowledge, there being difficulty understanding exactly what this might mean for Indigenous Peoples and local communities with different cosmologies that treat the policy and law about genetic resources in different ways, <sup>104</sup> and the appropriate protocols for engagement with Indigenous Peoples and local communities about their traditional knowledge.

The policy and law machinery of ABS is also likely to be a major focus of future literature. In some regions and countries, implementation of ABS is decentralized with competences based on a territorial scale allowing governing of genetic resources and traditional knowledge at national, sub-national and local levels. While this allows for greater autonomy for individual nations or states/provinces in relation to their own genetic resources, the strong horizontal division of competences may result in significant overlap between different relevant administrative sectors. For example, in Greece, the management of access to biological material for research purposes differs depending on the subject of the research. 105 Hence the authority in charge of granting permits might be different from one event of access to another even if they concern the same genetic resources. The Nagoya Protocol has been important in establishing mechanisms for national focal points (for information about how to do ABS) and competent authorities (for carrying administration of ABS) (Nagoya Protocol, Article 13). These administrative mechanisms can also be

important as checkpoints to ensure users properly comply with their ABS obligations (such as prior informed consent and mutually agreed terms) and for providing important provenance materials like internationally recognized certificate of compliance (Nagoya Protocol, Article 17). How the various countries establish this policy and law machinery and how this will operate efficiently will need to be researched and assessed. This will be critical as overly complicated processes, high costs and lengthy delays will undermine ABS as potential users seek other alternatives and undermining ABS.

#### 5. Conclusion

This SQLR of the ABS literature about genetic resources, associated information and associated traditional knowledge in the different geographic regions reveals a vibrant body of literature exploring a range of key topics. It identified four themes across regions: (1) development and implementation of ABS policy and law; (2) the interaction of intellectual property with ABS; (3) the interaction of traditional knowledge systems with ABS; and (4) ABS issues concerning research, development and commercialisation. The exploration of these themes varied significantly between regions. While all regions had a similar emphasis on ABS policy and law (theme 1), the review found that North and South America dominated intellectual property analyses (theme 2), Africa, Asia and Oceania dominated traditional knowledge analyses (theme 3) and Europe dominated research and development analyses (theme 4). All regions had a similar emphasis on literature concerning commercialisation and bioprospecting (theme 4). These trends may shed light on the relative importance to regions of these themes for policy makers in their development of ABS measures. On the other hand, they may be an indication of gaps in research analysis for each region.

A key finding of this review is that academic analysis has largely focused on a few key countries in each region – Africa (South Africa), Asia (India), Europe (Norway), Oceania (Australia), North America (USA) and South America (Brazil). Across all regions, the major gaps in analysis were about the effectiveness of ABS measures achieving their conservation, sustainable use and equity objectives.

We hope that the contributions from the presently unrepresented countries of the world are included in future literature. These voices are important for policy makers to understand the diversity of approaches that countries are taking to fulfil their obligations under the CBD and Nagoya Protocol and the agreement's biodiversity and equity objectives.

There is little evidence about whether a common or a diverse approach to ABS implementation at regional and/or national levels is more effective for achieving these objectives. Building this body of evidence would require researchers or policy makers to assess the different approaches and uncover the costs, benefits and effectiveness of each in the context of biodiversity and equity objectives. This is difficult and complicated research because of the detail required for accurately documenting each country approach within a comparative analysis. However, this would be a critical step towards promoting communication and understanding among academia, government, business non-governmental organisations about the ABS concept and whether it can deliver concrete biological conservation, sustainable use equitable outcomes.

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# Supplementary material

The supplementary material is available in the electronic version of this article: https://dx.doi.org/10.3233/EPL-201028.

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