Introduction

The conservation of biological diversity (hereafter biodiversity)[1] and the ability to continue to use biological resources sustainably are amongst the most pressing issues that the world currently faces. Balancing the protection of ecosystems, which involve a plethora of animal, plant and microbial species, with sustainable development objectives demands a systematic response at the international, regional, national and sub-national levels by a myriad of actors. The effective preservation of biodiversity cannot be met through environmental protection laws alone. A critical problem is one of incoherence – i.e., the situation where laws, policies and regulations designed to protect biodiversity and to encourage its sustainable use and development are not established in a consistent and mutually supportive manner with laws, policies and regulations in other domains, such as industrial policy or intellectual property (IP), that have an impact on biodiversity.

In order to address the linkage between biodiversity conservation and its sustainable use, the Convention on Biological Diversity (CBD) introduced as one of its three objectives the fair and equitable sharing of the benefits arising out of the utilization of genetic resources with those providing such resources. The inclusion of access and benefit sharing (ABS) as an objective of the CBD was based on the premise that biodiversity has been used by public institutions and private entities to produce new knowledge and products that brought various benefits to its new users, but not necessarily for its original owners or custodians. It is the ABS aspect that entails the greatest interface between IP rights and biodiversity issues.

Clear, fair and equitable rules on ABS are critical to prevent the misappropriation of genetic resources and associated traditional knowledge (TK), a situation also sometimes referred to as 'biopiracy'. Narrowly defined, misappropriation refers to access to and use of genetic resources without prior informed consent and/or mutually agreed terms pursuant to the national access legislation of the country providing the genetic resources and applicable international rules on access and benefit sharing.[2] One means by which genetic resources can be misappropriated utilizing the IP system is when, for example, a company sources biological resources from a country without consent, utilizes that resource in R&D to develop an invention, and then attempts to patent that invention utilizing the resource without any benefits to the provider, or without mentioning where the resource was obtained. Civil society organizations have cited as an example of misappropriation the attempted patenting of products by a Swiss company that contained rooibos and honeybush, as described in the box below.

[1] According to Article 2 of the CBD, 'Biodiversity/Biological Diversity' consists of the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic systems and the ecological complexes of which they are part; this includes diversity within species (genetic), between species and ecosystems. Biodiversity is a term describing variability, whereas 'ecosystem' describes a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.

[2] This view is based on the definition proposed by Switzerland for WG-ABS 9 on 18 February 2010 regarding the need for definitions in the lead up to COP 10 at Nagoya, Japan.

Box 1
Patent Applications on Rooibos Products

Nestlé, the world's largest food company, [faced] allegations of biopiracy after it applied for patents involving two plants found in South Africa without having negotiated permission to use them with the South African government.

In what they have dubbed the "rooibos robbery," the Berne Declaration, a Swiss advocacy organisation, and Natural Justice, a South African environmental group, [accused] Nestlé of having violated South African law and the Convention of Biological Diversity (CBD).

At issue are two plants found in South Africa, rooibos and honeybush, both of which are commonly used to make herbal teas. Nestec, a Nestlé subsidiary, filed four international patent applications for using the plants or extracts from them to treat hair and skin conditions such as acne, wrinkles, and hair loss. A fifth application sought patent protection for using rooibos as an anti-inflammatory. It is seeking patent protection in a large number of countries around the world, including South Africa.

Benefit-sharing a key issue

According to Natural Justice and the Berne Declaration, the South African Biodiversity Act — the country's implementing legislation for the CBD - requires companies to get a permit from the government if they intend to use South African genetic resources for research or patenting. These permits can only be obtained with a benefit-sharing agreement.

In a press release, Natural Justice and the Berne Declaration said that South Africa's department of environmental affairs told them that Nestlé never received permits to use rooibos and honeybush.

"Based on the information provided," the groups said, "it is clear the patents of Nestlé and the research on which they are based are in contradiction with South African law and the CBD."

Although best known for food product brands such as Nescafe, Nespresso, and Gerber, Nestle is active in the cosmetic industry. It owns over a quarter of l'Oréal, the world's largest cosmetics firm; the two companies together own Laboratoires Innéov, a nutritional cosmetics venture.

"Nestlé builds its new business on illegally accessed material, precluding South Africa of their rightful share of benefits. Such illegal behaviour must no longer be supported by the patent system and tolerated by our governments," said François Meienberg of the Berne Declaration.

Plants not sourced in South Africa, Nestlé says

Nestlé … rejected the accusations. According to a report in the South African newspaper Business Day, company spokesman Ravi Pillay said that Nestlé had neither sourced the plants in South Africa nor done research on them there. South African suppliers had provided rooibos and honeybush extracts and material to two Nestlé research facilities in Switzerland and France, which then used it for basic research on active ingredients.

Following this research, he said, Nestec filed several patents to protect its research results, which showed potential benefits for consumers.[3] "Nestec has not filed any patent relating to the plants themselves, or extracts of the plants. Nestlé has not made any commercial use of these patents, and has no plans to do so in the near future," he added.

Pillay said that if Nestlé decided to use the patents commercially, it would comply fully with the benefit-sharing provisions in South African law.

However, Johanna von Braun of Natural Justice in Cape Town said that, under South African law, the commercial phase of bioprospecting begins once a patent application has been filed. At this early

[3] Note by the authors: these patent applications later failed pre-examination by the World Intellectual Property Organization (WIPO).

phase, a permit - which would include a benefit sharing agreement and a material transfer agreement - has to have been submitted regardless of where the research takes place, she said.

Von Braun said that the companies that supplied the rooibos and honeybush to Nestlé had also not secured permits.

International law unclear on "ex-situ" resources

There is a lacuna in international patent law about who owns genetic resources once they have been removed from their country of origin. The Convention on Biological Diversity clearly specifies that genetic resources are under national sovereignty. But it is less clear about Nestlé's responsibilities vis-à-vis genetic resources from another continent supplied to it in Europe.

South African law, however, is quite clear: it specifies that all indigenous biological resources are those historically from South Africa.

The terms under which the South African suppliers provided the plants to Nestlé mattered, von Braun explained. "If they're exporting rooibos to make tea, they don't need a permit. But if they were going to be used for research, the suppliers would have needed an export permit including a bioprospecting application from Nestlé."

Since 2002, parties to the Convention on Biological Diversity have been negotiating an international regime on access and benefit sharing. This would create firmer rules about the use of genetic resources, including so-called "ex situ" resources that are no longer in their country of origin.

"The Nestlé case highlights the urgent need of a new protocol that prevents the misappropriation of genetic resources and associated traditional knowledge," said Kabir Bavikatte from Natural Justice. "Only a strong protocol will protect developing countries from an unlawful exploitation by companies."

Source: Reproduced with permission from International Centre for Trade and Sustainable Development (ICTSD), originally published in *Bridges Trade Biores*, Vol. 10, No. 10, 31 May 2010.

As misappropriation of genetic resources is not a defined legal term, however, it is possible to define misappropriation of genetic resources and associated TK more broadly. Aside from compliance with ABS legislation, misappropriation through the IP system could also potentially occur when a firm or person in a user country attempts to obtain exclusive rights over proprietary names associated with a genetic resource or related TK to the exclusion of its providers, without his or her consent. The effect of allowing such marks to be registered would be to allow the registrants to take advantage of the goodwill represented by the mark without attribution or compensation to the providers. One example often cited in academic literature are the attempts by coffee bean distributors in developed countries to obtain global trade name rights to various Ethiopian coffees such as *Sidamo*, notwithstanding that those local communities had obtained geographical indication rights to the coffees grown in their respective regions. In this regard, Robinson has suggested a typology of problematic activities, which include patent-based biopiracy and non-patent based biopiracy and misappropriation.[4]

At present, it may not be possible to quantify the extent of misappropriation of genetic resources and associated TK as many of the underlying contracts to transfer genetic resources remain private and confidential. The new ABS regime, discussed herein, whereby information on when resources have been accessed with permission based on mutually agreed terms would be registered nationally and internationally, will hopefully go some way to address this

[4] Robinson (2010).

information deficiency. Nonetheless, various sources have documented examples of potential misappropriation, and the problem remains one of concern particularly to provider countries.[5]

The contentiousness of the negotiations at Nagoya in the fall of 2010, which set up the treaty laying down international rules on ABS under the CBD (the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD, hereafter the Nagoya Protocol) is perhaps a reflection of the difficulty in reaching agreement at the multilateral level in this day and age. Divisive issues were routinely excluded from the final text in search of a wording that is minimally acceptable to all of the negotiating parties. The result is far from satisfactory for most stakeholders. One could possibly conclude that it was a miracle that an agreement was reached that contained at least some definitive rules on ABS of genetic resources and associated TK, even though many important issues were left out of the final text. To be fair, no treaty can be expected to cover all aspects of a topic, and there will always be gaps where additional work is needed to examine how different legal regimes need to be configured to work in synergy, rather than in conflict.

This handbook is thus designed as one means to begin to fill the gap in understanding where the treaty text has chosen to remain silent. *The Convention on Biological Diversity and the Nagoya Protocol: Intellectual Property Implications* addresses how the global rules on ABS of genetic resources and associated TK should work in tandem with an area that is mentioned minimally in the 2010 Nagoya Protocol, i.e., IP. Specifically, this handbook is designed to show the complexity of relevant IP policies that have an impact on various aspects of the CBD and the Protocol, particularly from the provider country perspective. It is all too easy and simplistic to see IP as a stream of cash rents that derive from certain granted exclusive rights that could potentially be shared as benefits. Our view of IP is necessarily much broader, examining when it is (and when it is not) appropriate to grant such rights, how the application process can generate important information that could assist in the implementation of the ABS rules, when such rights are subject to important exceptions and limitations on policy grounds, and when traditional IP instruments such as patents may not make much sense for protecting certain intellectual or creative endeavors.

Chapter 1 starts with an overview of the ABS system as established by the CBD and the Nagoya Protocol, highlighting the obligations of countries and the international community to put in place national ABS legislation and the administrative machinery to ensure that countries meet their treaty obligations. Because of an absence of clarity in these two treaties on many important issues, however, it is necessary to look to other sources of law to fully understand the relationship between IP and ABS. Chapter 2 therefore follows with a complementary examination of various other treaties and policies that govern and shape the rules on IP and ABS. Particular emphasis is given to an examination of IP treaties such as the TRIPS Agreement, which gives some minimum measure of uniformity among the signatories' respective legislation on IP. As seen in the later chapters, though, the language contained in both the CBD/Nagoya Protocol and the TRIPS Agreement is the result of political negotiations and therefore leaves a good deal of 'policy space' or 'flexibility' for countries to tailor their national legislation so as to support important policy objectives, including when read in conjunction with important international policy statements such as the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP).

[5] See Vivas-Eugui (2012), Box 1 for some well-known examples.

An area where there is clearly potential for the IP regime to support the ABS regime is disclosure (Chapter 3). Patent applicants must disclose material information when they seek to obtain exclusive rights over a technology. This could potentially include the country of origin of genetic resources or associated TK contained in an invention, whether the invention is a product or process. The idea behind this is to make transparent and subject to public scrutiny whether ABS obligations have been met and to ease the identification of potential cases of misappropriation at the point of time someone applies for a patent. While disclosure has to date been discussed in the lead up to the Nagoya Protocol negotiations, at the TRIPS Council and at the World Intellectual Property Organization (WIPO), no intergovernmental body has to date mandated disclosure of origin or source when applying for a patent as an international legal obligation, and there has been no dispute settlement case at the World Trade Organization (WTO) that tests the limits of a disclosure requirement. From the perspective of a provider country, the weakness of disclosure of origin/source requirements in the absence of an international requirement to include them in national legislation is that while a provider country could require disclosure, there is no guarantee that user countries would similarly require disclosure.

There are a number of different ways in which disclosure of origin can be woven into a patent law. This could include, for example, requiring proof of legal provenance to simply assuming that disclosure of origin is required under a generic obligation to disclose material information relevant to the patent application, without specific reference to the origin or source of genetic resources and associated TK. A disclosure requirement could similarly be woven into plant variety protection legislation, provided a country is are not under any treaty obligation to refrain from doing so.

Beyond disclosure of origin, chapter 4 examines a wide range of IP tools that could potentially be harnessed to support the CBD/Nagoya rules on ABS. One set of measures are those that can keep certain genetic resources from being patented, i.e., excluding discoveries, gene sequences, pathogens and naturally occurring biochemical compounds from the scope of patentability. Another set of measures deals with protecting certain activities from liability notwithstanding the existence of a patent so as not to impede innovation, or for other good policy reasons as in the research and experimentation exception (and its variant in plant variety protection laws) and the medical treatment exception. A final set of measures include theories to invalidate a wrongly granted IP right, including the judicial doctrine of 'clean hands' and violations of public morality and order, among other theories. Chapter 4 makes clear, however, that the law in many of these areas is still very much developing. For example, New Zealand's proposed approach of treating patent applications that contain Maori TK as presumptively a violation of public morality has yet to be tested and the issue of the patenting of gene sequences was recently considered by the Supreme Court of the United States.[6]

Chapters 5 and 6 of this handbook deal with two aspects of IP law that could potentially support the ABS system in so far as they are designed to create rights for local and indigenous communities in provider countries that use genetic resources in their daily life, and associated TK. A number of countries have passed legislation that gives rights to indigenous and local communities (ILCs) over their TK and traditional cultural expressions (TCEs). Such *sui*

[6] *Association for Molecular Pathology et al. v. Myriad Genetics, Inc et al.* **(**Case No. 12-398, slip op, decided by the Supreme Court of the United States on 13 June 2013).

generis legislation is often necessary because Western notions of IP law such as patents and plant variety protection are not always an effective vehicle to provide the local community with proprietary rights. While there are many policy goals that are pursued by such a *sui generis* regime, these laws are designed to be both defensive and offensive from a provider country perspective, i.e., so that the TK/TCE is not misappropriated, but also to give the local and indigenous community a chance to exploit the TK/TCE to secure benefits in the event that the TK/TCE can be commercialized. The scope of such laws can potentially cover practices such as farming techniques and traditional medicine. Chapter 5 highlights that these laws, in particular, need to be interpreted in the context of international human rights instruments that recognize the various customary rights of indigenous peoples. Most of these laws are relatively new, however, and it could very well be said that many countries are still struggling to define the contours of a law that would grant to ILCs a set of enforceable and exploitable rights.

Chapter 6 examines the power that distinctive signs can have to help secure benefits for biodiversity derived products from provider countries and how they can help protect TK. Distinctive signs cover a range of IP instruments including trademarks, collective trademarks, protected geographical indications (PGIs), protected denominations of origin (PDOs) and certification marks (see Table 2, Chapter 6). The broad objective behind these tools is to communicate certain information to a potential buyer of a product to which a distinctive sign is affixed. To the extent that the sign adds value to the product upon which it is affixed, the sign or mark can be used to secure benefits. In the case of PGIs and PDOs, the mark certifies quality and originality linked to a specific location. Certification marks indicate to a consumer that certain procedural and quality standards are met. While trademarks are simple indications of distinctiveness that a trademark holder may affix on a product for which that mark is registered, collective trademarks, which are privately owned by a group of proprietors, are potentially useful when certain practices are not able to be defined by geography as in the case of PGIs and PDOs.

The Chapter also points out the difficulties of managing and maintaining these distinctive marks. Such difficulties include determining the geographical coverage and the standards that must be met in order to be able to use a sign, how to maintain the quality that the sign stands for and how to enforce the signs abroad in order to prevent misappropriation. The rural populations of provider developing countries and ILCs are often ill prepared and under-resourced to be able to effectively manage the systems that govern certain distinctive signs. A final remark on signs from the perspective of the CBD is that to the extent that the signs are promoting the consumption of resources abroad, there is a need to be conscious about how mass consumption may affect sustainable practices.

Finally, Chapter 7 looks at how ABS and IP laws are reflected in private contracts which cover the physical transfer of genetic resources. Such private contracts are referred to in the CBD and Protocol as benefit-sharing agreements, and can take the shape of material transfer agreements (MTAs), collaborative research agreements, bioprospecting agreements and the like. The handbook starts by explaining the difference between MTAs over genetic resources and contracts where physical transfer of a private object confers a complete transfer of ownership. To the extent that genetic resources are subject to the sovereign jurisdiction of the provider country, the agreement is one that merely permits access to the resource and governs the provisions on what the transferee may do with the genetic resource.

In contract negotiations, issues that could potentially be difficult to ascertain are, *inter alia*, who the owners of a genetic resource are when local and indigenous communities are involved, the description of the genetic resource being transferred, what research is permitted with the resource and how to handle IP applications from the fruits of that research, what benefits will be shared, whether third party transfers will be permitted and what happens to the resource after the voluntary or involuntary termination of the agreement. Effective negotiation takes practice and an understanding of the underlying laws and principles. ABS authorities in provider developing countries and local and indigenous groups may be at a disadvantage in effectively negotiating contract terms with the lawyers representing biotechnology, cosmetic and pharmaceutical firms based in developed countries.

If there is an overall message that carries through all seven chapters of this handbook, it is that many, if not most, of these areas are as yet developing areas of law and policy. As such, countries are very much experimenting with various models of IP protection and ABS. For example, Switzerland's disclosure regime differs significantly from disclosure in the Andean countries; many countries are only just beginning to introduce *sui generis* regimes for geographical indications; and judicial interpretation of laws on the patenting of gene sequences in the developed countries has rarely been consistent. The example of *sui generis* laws on TK and TCEs shows that no country has yet come up with an optimum model law that works satisfactorily.

It is therefore far too early to be talking about 'best practices'. The slow pace of progress at intergovernmental negotiation forums discussing the relationship between IP and ABS is perhaps a reflection that the interface has not yet reached a level of maturity where additional global consensus for regulation would be 'ripe'. There is, however, much to learn from each country's experience in implementing IP and ABS legislation, as well as other flanking legislation such as those governing ILCs, in a manner that is mutually supportive. For this reason, the handbook cites as many examples of existing policies as possible. Moreover, the TRIPS Agreement and the CBD/Nagoya Protocol provide ample room for policy makers to experiment and to revise their national legislation as necessary, given each country's unique circumstances.