Sharing of Benefits

14

Doris Schroeder

Introduction

Benefit sharing is a legal term used in the context of access to and utilization of biological resources. The term describes an exchange between those who grant access to a particular resource and those who provide compensation or rewards for its utilization. For instance, in 2000, a US-based biotech corporation (Diversa) signed an agreement with a South African research institute (CSIR) to obtain access to South African microorganisms. In return for such access, Diversa supports the CSIR's bioprospecting activities and pays royalties on any successfully developed products. The above exchange is typical for a benefit-sharing agreement as governed by the UN Convention on Biological Diversity (CBD, 1992).

On a broader understanding of benefit sharing, results from scientific research should be shared with society as a whole and not only with those who provide access to resources. This more aspirational meaning of benefit sharing is expressed, for instance, in the UNESCO's Universal Declaration on Bioethics and Human Rights (2005). The main governance instruments for benefit sharing are listed in Table 14.1. The Declaration of Helsinki, the Convention on Biological Diversity, and the UNESCO Universal Declaration on Bioethics and Human Rights will be discussed in more detail in this chapter.

This chapter examines both aspects of benefit sharing and aligns them with different conceptions of justice. The access and benefit-sharing requirements of the CBD – which covers plants, animals, microorganisms, and traditional knowledge – will be described as a justice-in-exchange mechanism. The same applies to the benefit-sharing provisions for human biological resources through post-study access to successfully tested medical interventions or alternative benefits. The distributive justice and human rights aspects of benefit sharing will be examined using the above mentioned UNESCO declaration. Four case studies are added to illustrate the challenges occurring in all areas of benefit sharing.

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Three Benefit-Sharing Instruments

The Convention on Biological Diversity

In 1992, a UN conference of unprecedented size and scope was held in Rio de Janeiro. What became known as the "Earth Summit" provided a platform for discussing the ongoing destruction of global biodiversity. Almost 10,000 on-site journalists covered the summit, and its main output was the Convention on Biological Diversity (CBD). The CBD recognized that the conservation of biodiversity is a "common concern of humankind."

The legally binding convention has 193 Parties (the world minus the United States of America (USA) and Andorra). It has three major objectives:
The conservation of biological diversity
The sustainable use of its components and
The fair and equitable sharing of benefits from the use of genetic resources

The first objective relates to the common interest of humankind, namely, to deal with the serious loss of biodiversity and its potential implications for ecological functions as well as future technoscientific uses. The twentieth and twenty-first century witnessed the disappearance of species at 50–100 times the natural rate. The figure had risen to 100–1,000 times the natural rate in 2010 and may accelerate to 1,000 or 10,000 times by 2020. The second objective relates to user requirements for the long-term availability of resources, for instance, in scientific or commercial endeavors or to support human livelihoods. The third objective summarizes the demands made by developing countries since the 1970s, namely, to require users to share benefits with resource providers in order to avert exploitation. The Convention on Biological Diversity covers plants, animals, microorganisms, and related traditional knowledge.

To understand the established legal meaning of benefit sharing, it is important to consider why resource use can be exploitative (see Box 14.1 for a definition of exploitation).

Box 14.1: Exploitation
Exploitation is a failure to benefit others as some norm of fairness requires leading to wrongful gain on the one hand and undeserved loss on the other (Mayer, 2007). Three forms of exploitation can be distinguished:

In type 1 exploitation, exploiters fail to benefit other parties *at all* even though they ought to. For instance, public transport users who "dodge" fares are exploiters type 1 or free-riders.

In type 2 exploitation, exploiters do not benefit others *sufficiently*. In this case of exploitation, an exchange takes place, but it does not benefit both parties fairly. One party gains disproportionately, while the other loses out. For instance, a landlord might exploit a recent immigrant's ignorance of local rents and overcharge her.

In type 3 exploitation, exploiters do not benefit others *authentically*. Exploiters might give others what they want and at a fair price, but the exchange does not genuinely benefit them. For instance, the purchase of heroin might be what buyers want and it might be sold at a competitive market price, but they would nevertheless be harmed by the exchange when judged from a neutral standpoint.

Why should a European researcher who uses an African plant in product development be hampered by access and benefit-sharing requirements of a legally binding international convention? Why not assume that the resulting product, for instance, a new medical drug, will benefit humanity as a whole and leave scientists unencumbered by costly bureaucracy?

Indeed, prior to the adoption of the CBD, nonhuman biological resources and traditional knowledge were frequently regarded as the common heritage of humankind. Bioprospectors were able to take resources out of their natural habitat or make use of traditional knowledge to develop commercial products without sharing benefits with states or local communities. This approach was justified on the premise that the planet's biodiversity ought to be shared among humankind rather than being fenced in by individual states.

The idea of the common heritage of humankind entered the canon of international law in the 1970s and 1980s with the conclusion of two UN brokered international treaties: the Agreement Governing the Activities of States on the Moon and Other Celestial Bodies (1979) and the Convention on the Law of the Sea (1982). These treaties declared that the seabed, the ocean floor, its subsoil, as well as the surface and subsurface of the moon should not become the property of any state, organization, or individual. Instead, they were regarded as the common heritage of humankind. But what does the common heritage principle mean? There are two conflicting interpretations exemplified respectively in the initial text (1982) and subsequent revision (1994) of the Convention on the Law of the Sea. One interpretation is that the common human heritage must be used and enjoyed on terms that benefit all. The other is that the common heritage is available to be used and exploited at will on a first-come, first-served basis.

In preparatory negotiations for the CBD in the late 1980s, academics, activists, and politicians from around the world started to point out that the latter interpretation of the common heritage was predominant in cross-border research activities involving biodiversity. This was not surprising given the uneven playing field in science and innovation (see Diagram 14.1 on the technological divide and Table 14.2 mapping biodiversity against poverty).

As can be seen from Table 14.2, the burden of serious poverty and the availability of mega-biodiversity align in most cases, with only a few exceptions. Given in-country lack of resources for investment in science and technology, it is clear that most scientists who access mega-diversity are from the north. If this is

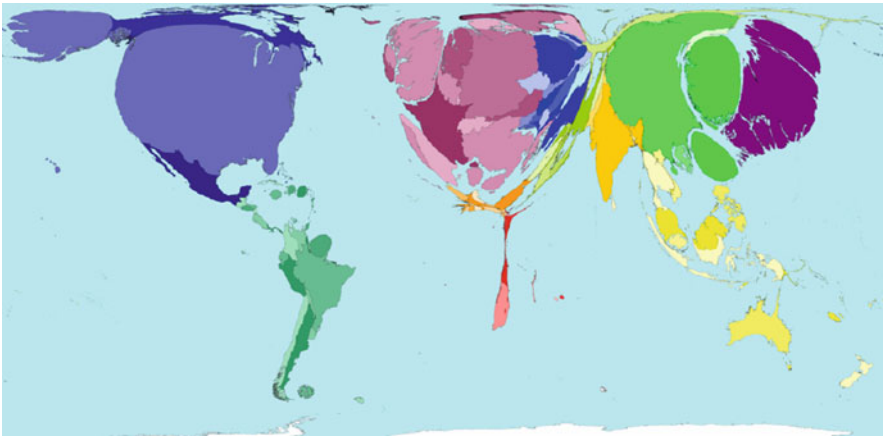

Diagram 14.1 Research and development expenditure in 2002, WorldMapper (© Copyright SASI Group (University of Sheffield) and Mark Newman (University of Michigan))

Table 14.1 Main governance instruments for benefit sharing

Benefit sharing (established sense)	Benefit sharing (aspirational sense)
Convention on Biological Diversity (1992) including national laws: e.g., Biodiversity Bill India 2002, Biodiversity Act South Africa 2004 and including Nagoya Protocol, 2010	The Universal Declaration of Human Rights, 1948, Article 27(1)
	International Covenant on Economic, Social and Cultural Rights, 1966, Article 15(b)
CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002, Guidelines 5, 10 and 21.	Council of Europe's Convention on Human Rights and Biomedicine, 1997, Preamble
Declaration of Helsinki, 2008 including national laws: e.g. Brazilian National Health Council resolutions 1996, 1997, 1999, 2000	Human Genome Project's Ethics Committee Statement on Benefit Sharing (2000)
	UNESCO Universal Declaration on Bioethics and Human Rights (2005)

combined with a prior history of colonial exploitation and its consequences to this day, it can be argued that an unfair first-come, first-served system to resource use was being practiced rather than the more benign version of the common heritage of humankind principle (Shiva, 1991). In short, resource use was being exploitative (type 2 exploitation from Box 14.1).

Worldmapper uses a technique to resize territories with regard to some subject of interest. Diagram 14.1 is a world map resized according to research and development expenditures in 2002. Africa hardly appears on the map, while the industrialized north appears particularly bloated.

In July 2000, the World Conservation Monitoring Centre named 17 countries as mega-diverse countries: Australia, Brazil, China, Colombia, Democratic Republic

Table 14.2 Poverty and mega-diversity

Country	% <2$/day
Madagascar	89.6
Congo (DRC)	79.5
India	75.6
Papua New Guinea	57.4
Indonesia	46.0
Philippines	45.0
South Africa	42.9
China	36.3
Colombia	27.9
Peru	18.5
Ecuador	12.8
Brazil	12.7
Venezuela	10.2
Malaysia	7.8
Mexico	4.8
Australia	..
United States	..

of the Congo, Ecuador, India, Indonesia, Madagascar, Malaysia, Mexico, Papua New Guinea, Peru, the Philippines, South Africa, the United States of America, and Venezuela. Combined, these 17 countries host more than 70 % of the earth's species. The above table matches these mega-diverse countries with 2009 data of percentage of population living on or under the US$2 a day poverty line.

To address the common concern of humanity, namely, the depletion of biodiversity, developing countries demanded an end to one-sided resource use by foreign parties. Given that most repositories for biological resources were situated in the south (see Table 14.2), these were used to negotiate for concessions from developed countries. In the end, these concessions were:

- Sovereignty over genetic resources to be lodged with national governments, and no longer considered the common heritage of humankind
- A legal framework for dealing with biotechnology, in particular, those aspects that pose a threat to safety (leading to the Cartagena Protocol on Biosafety in 2000)
- Recognition of indigenous communities as the guardians of biodiversity and related traditional knowledge
- The requirement to share benefits with the providers of genetic resources, with their prior informed consent (PIC) and on mutually agreed terms (MATs)

The latter was the birth of benefit sharing as enshrined in the CBD's third principle, "the fair and equitable sharing of benefits from the use of genetic resources." To return to the question at the outset: why should a European scientist be hampered by bureaucracy when developing new products based on nonhuman

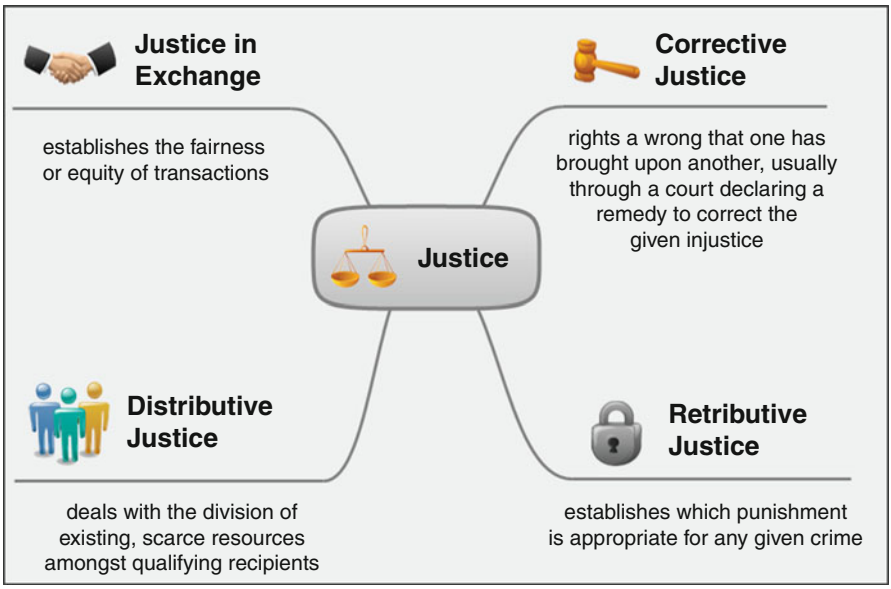

Diagram 14.2 Principles of justice

biological resources and associated traditional knowledge? Two answers are important.

The first answer is that 193 states, in other words, the world without the USA and Andorra, agreed that while the progress of science can be beneficial to humankind as a whole, it should not be based on yet another instance of wrongful expropriation of resources given the long history of colonialism.

The second answer must make reference to justice. Philosophers usually distinguish four types of justice principles, as illustrated in Diagram 14.2. The relevant principle in the context of access to resources is justice-in-exchange (Schroeder and Pogge, 2009).

Justice-in-exchange establishes the fairness or equity of transactions. It regulates the justice of giving one thing and receiving what is due in return. An interaction is considered just if all parties in the exchange receive an appropriate return for their contribution. A hidden, implicit element of justice-in-exchange is that the parties must agree voluntarily to the exchange. If something is taken from one party against their wishes, it does not make the transaction ethical simply to compensate them appropriately. Hence, what is termed prior informed consent in the context of the CBD is part of a just approach. It is an essential first step, a process requirement to achieve a just outcome.

For Aristotle, the fairness of a transaction could be judged by an outsider. The intrinsic worth of something, say a set of books, a supply of antiretrovirals, or South African microorganisms, had to be matched by a return, either in kind or in

monetary terms. Certain prices would have been deemed disproportionate by Aristotle, whether they were paid voluntarily or not. Hence, the fairness of a transaction relied on a judgment that the items exchanged were what Aristotle referred to as proportionate requitals.

Today, an understanding of justice-in-exchange based on Roman law is more common. This only requires that two competent adults (or parties) have agreed on the transaction. If somebody is willing to pay a thousand dollars for a set of books, so be it. The interaction would be considered just if the seller and the buyer had agreed on it without coercion or deceit.

What then is the second answer to the question of why a European scientist should be hampered by bureaucracy when developing new products based on nonhuman biological resources? The answer is to establish fairness in exchange. When it comes to biological resources, be they plants or microorganisms, the ideal scenario would let them be freely accessible to be used for the benefit of humankind without any inherent exploitation. In this scenario, the fair return would be access to a new product, a much needed drug for instance. Those who access resources would share the resulting benefits equitably with others. Bureaucratic barriers to the use of resources (other than for reasons of achieving sustainability) and requirements of benefit sharing would be counterproductive in a benign context where all human beings would have access to the fruits of innovation through the market. Free access to biological resources would facilitate innovation enjoyed by all, much in the spirit of the common heritage idea. But we do not live in a world thus organized. In fact, in the context of a severely unjust international economic order, which disrespects human rights (Pogge, 2008), one needs to – at the very least – avoid the most blatant exploitation, namely, that a person or a group provides access to a resource without *any* return whatsoever. Where appropriation by some (on a first-come, first-served basis) will lead to innovations unavailable to the poor, it makes sense – ethically – to fence in resources with bureaucratic procedures to aim for justice-in-exchange.

To put it simply: *those who contribute to scientific research and innovation ought to share in the resulting benefits*. If benefit sharing with the contributors of biological resources and related knowledge does not take place, scientific advancement is exploitative. For short descriptions of two cases, see Boxes 14.2 and 14.3 (for a short film on the Hoodia case, download here: http://extras.springer.com/2009/978-90-481-3122-8/).

While it is clearer now what benefit sharing according to the CBD means, it may not be clear what counts as a benefit. However, a long list of examples was given with the Nagoya Protocol. The adoption of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was a most promising development on benefit sharing. The protocol was adopted on 30 October 2010 at the tenth meeting of the Conference of the Parties to the CBD. Adoption was achieved through a consensus decision among the 193 parties, following some 6 years of intense negotiations – which frequently pitted developed countries against developing countries, and providers of genetic resources against users of those resources.

Box 14.2: Hoodia and Skeletium Cases

One of the best known benefit-sharing cases is that of the San Hoodia (Wynberg & Chennells, 2009). The San peoples, also known as Bushmen of the Kalahari, are the oldest human inhabitants of Southern Africa. For thousands of years, they lived as the sole occupants of an area stretching from the Congo-Zambezi watershed to what is now Cape Town. After centuries of genocide and marginalization imposed by colonialists, they now number approximately 100,000 people in Botswana, Namibia, South Africa, and Angola.

Their lives today are characterized by abject poverty. Yet they still possess traditional knowledge covering the biodiversity of southern Africa. This includes knowledge about the appetite-suppressant properties of the *Hoodia* succulent – a plant used in the past as a substitute for food and water when hunting.

In 1963, a South African research institute, the Council for Industrial and Scientific Research (CSIR), developed an interest in the plant. But they were unable to analyze its molecular structure until the mid-1980s when they acquired high-field nuclear magnetic resonance spectroscopy equipment. In 1995, after successfully isolating the appetite-suppressant properties, the CSIR filed for a patent. In the same year, South Africa became a party to the Convention on Biological Diversity. This meant that those using the traditional knowledge needed to obtain consent from the holders of such knowledge and negotiate a benefit-sharing agreement with them.

The CSIR never made contact with the San. Instead, the institute sublicensed its discovery to firms in Europe and the USA. A vigilant local NGO informed San leaders that their traditional knowledge had been used in a patent application and that they could either challenge the patent or demand a benefit-sharing agreement. They chose the latter.

In March 2003, the San and the CSIR signed a historic agreement which will give the San 6 % of all CSIR royalties received from license holders and 8 % of all milestone payments. Payments of around 100,000 US$ have already been received into a benefit sharing Trust. However, Pfizer and Unilever, two high-profile sublicensees, have both dropped their Hoodia product development, and in the late 2012, the future of this high-profile benefit-sharing agreement is uncertain. However, members of the San community have benefitted from capacity building, especially in matters of law and negotiation. More positively though, further benefit-sharing agreements have been negotiated.

In 2008, another agreement was concluded between the San peoples and HGH Pharmaceuticals (Pty) Ltd. The agreement covered the antidepressant properties of the *Skeletium* plant and has to date led to an income of around 80,000 US$. The company has developed the product and has completed all required efficacy and safety compliance tests required for the US market. A resulting product will be released in the second quarter of 2012.

Box 14.3: Nicosan (Formerly Niprisan) Case

Sickle cell disease is a genetic disorder which is endemic in Sub-Saharan Africa. Each year, around 300,000 babies are born with the potentially life-threatening disease or a variant. Those who survive will suffer from recurrent painful crises, which will disrupt their lives continuously. Until recently, only palliative measures were available for affected patients. However, a Nigerian traditional health practitioner (the late Rev. Ogunyale) had developed an herbal medicine recipe, which was promising.

In 1992, a memorandum of understanding (MOU) was signed between Rev. Ogunyale and the Nigerian National Institute for Pharmaceutical Research and Development (NIPRD) under the guidance of Prof. Charles Wambebe. Research commenced and led to patents granted in Nigeria, the USA, England, India, and 42 other countries in Europe, Africa, the West Indies, and the Americas between 1998 and 2000.

In 2002, a license was granted to USA company Xechem for global manufacture. A ceremony was opened by the Nigerian President to celebrate the fact that a medicine (then called Niprisan) was fully developed in Africa by African scientists to be marketed globally. The first limited production of the drug was undertaken by Xechem in 2006 while a manufacturing plant was commissioned to be built in Abuja. In 2008, the company filed for bankruptcy and the plant was closed.

The Nigerian government withdrew the license from Xechem and charged NIPRD with further production. However, in 2010, existing supplies ran out and the drug became unavailable. The research and development of Nicosan (the drug's new name) ceased at the NIPRD in the same year.

While starting out as one of the most promising cases of using traditional knowledge to develop a medicine for a hitherto neglected disease, the results were highly depressing. While the MOU signed between Rev. Ogunyale and the NIPRD was adopted as an example of best practice by the World Health Organization (WHO) and the World Intellectual Property Organization (WIPO), no benefit sharing with the reverend or his community ever took place. The clinical trial participants who were involved to bring the drug to market have no access to the drug, not only because it is no longer manufactured, but also because it was too expensive for the poor during the short duration of being available for sale. Most frustratingly, though, a drug which addresses a serious disease that poses a major public health burden in Africa exists without being manufactured. A sufferer of the disease, Tosin Ola, expresses her severe disappointment in an interview with SciDevNet:

"Before Nicosan, I was in and out of the hospital on a monthly basis, having to have regular blood transfusions, countless IV [intravenous] sticks and daily pain. But, once Nicosan started working for me, the daily pain ceased and I have not been admitted into the hospital since 2008. The sad part is that people are dying every day and suffering needlessly in pain, while the treatment . . . is nowhere to be found" (Abutu, 2010).

1. Monetary benefits may include, but not be limited to:
   (a) Access fees/fee per sample collected or otherwise acquired
   (b) Up-front payments
   (c) Milestone payments
   (d) Payment of royalties
   (e) License fees in case of commercialization
   (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity
   (g) Salaries and preferential terms where mutually agreed
   (h) Research funding
   (i) Joint ventures
   (j) Joint ownership of relevant intellectual property rights
2. Nonmonetary benefits may include, but not be limited to:
   (a) Sharing of research and development results
   (b) Collaboration, cooperation, and contribution in scientific research and development programs, particularly biotechnological research activities, where possible in the party providing genetic resources
   (c) Participation in product development
   (d) Collaboration, cooperation and contribution in education and training
   (e) Admittance to ex situ facilities of genetic resources and to databases
   (f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favorable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity
   (g) Strengthening capacities for technology transfer
   (h) Institutional capacity-building
   (i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations
   (j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries
   (k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies
   (l) Contributions to the local economy
   (m) Research directed toward priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources
   (n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities
   (o) Food and livelihood security benefits
   (p) Social recognition
   (q) Joint ownership of relevant intellectual property rights

Not all of these benefits would be appropriate for benefit sharing in scientific research involving human participants, but the list gives a good idea of the diverse

Table 14.3 Main challenges for benefit sharing: Convention on Biological Diversity

Type of benefit sharing	Main challenges
Benefit sharing as justice-in-exchange 	Benefit sharing as justice-in-exchange could possibly be used by governments to neglect their duties to secure basic human welfare rights. However, benefit sharing cannot resolve distributive justice issues
	The emphasis in access and benefit sharing, as required by the CBD, must not move away from access. To obtain prior informed consent (PIC) before using nonhuman biological and associated traditional knowledge is essential
	The identification of traditional knowledge holders and their legitimate representatives remains a major challenge to achieving the goals of the CBD
	As CBD-style benefit sharing requires negotiations between users and providers of resources, unequal education, knowledge and skill levels are an impediment to just outcomes
	Managing the expectations of benefit sharing is a difficult task given that very few products ever achieve the commercial viability to lead to significant benefit flows
	Once a benefit-sharing agreement has been concluded, the expectations (as laid down in CBD-compliant national law) of Western-style governance can lead to significant tensions between users and providers of resources as well as auditors
	Resources do not respect national boundaries and benefit sharing involving several countries that can make claims to traditional knowledge, or biodiversity are difficult to handle legally
	Progressive international and national laws are not enough if poor, marginalized communities are not supported in claiming them
	The issue of benefit sharing for traditional knowledge should be promoted at the same time as the issue of land rights. However, only the UN Declaration on the Rights of Indigenous Peoples addresses both
	While the Nagoya Protocol has provided new impetus in resolving the lack of compliance with the CBD internationally, it is yet to be seen whether compliance can be achieved
	Last but not least, the fact that the USA is not a party to the CBD while being a major user of foreign biological resources poses significant ethical issues

possibilities for the sharing of benefits, far beyond profit-sharing. Before moving to benefit sharing as relevant to human resources, Table 14.3 summarizes the main challenges for realizing the spirit of the CBD.

The Declaration of Helsinki

The prevailing approach to benefit sharing for providers of human biological resources such as DNA or blood samples is the prescription of post-study obligations. Essentially, these obligations (previously known as post-trial obligations) describe a duty to provide human research participants with access to a proven beneficial health-care intervention after a study has been concluded. This means that in return for contributing to medical research, the research participants are meant to obtain access to any resulting products or interventions as a form of benefit sharing. One can see that the benefit-sharing spirit of the CBD is being maintained here too. Those who contribute to science ought to share in its benefits, to guarantee justice-in-exchange. However, it must also be noted that those who contribute to research outside the medical field, say cosmetics, are not necessarily guaranteed benefit sharing as the Declaration of Helsinki is unlikely to apply.

Post-study obligations within medical research were first introduced in the Declaration of Helsinki in 2000, when the WMA General Assembly in Edinburgh adopted paragraph 30:

> At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

This early formulation of post-study obligations was restricted to patients and, by implication, to trials involving volunteers in need of treatment. As a result, healthy volunteers enrolled in trials, as well as donors of biological materials, were excluded from benefit sharing. This focus on access to resulting products led to problems of equity. For instance, if post-study access to a drug is the only way to avoid the exploitation of research participants, those who take part in studies that do not lead to the marketing of a drug are excluded from benefits. Given that only a very small percentage of medical research eventually leads to products in pharmacies, this was a serious concern.

In 2004, the WMA's General Assembly in Tokyo added a note of clarification on paragraph 30, which opened the way for other benefits in addition to or instead of post-study access to successfully tested interventions (emphasis added):

> The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or *access to other appropriate care*.

To reduce the rigidity of post-study access to successfully tested drugs, the phrase "access to other appropriate care" was added. At the same time, the term "patients" was changed to "study participants," to allow for the inclusion of healthy volunteers. However, the term "trial" was retained, thus limiting benefit sharing to those taking part in clinical trials. This changed in the 2008 declaration, adopted in Seoul. Articles 14, 17, and 33 relate to benefit sharing. Article 14 deals directly with the issue of broadening the scope of beneficiaries from clinical trial participants to study subjects. It says (emphasis added):

> The protocol should describe arrangements for post-study access by *study subject*s to interventions identified as beneficial in the study or access to other appropriate care or benefits.

It follows, then, that all medical research involving human subjects which needs approval from an ethics review body should describe, in its study protocol, post-study access to successfully tested interventions or other benefits. This implies that donors of biological samples must be included among the possible beneficiaries, as the scope is not limited to "trials."

However, such a formulation gives rise to a practical concern, namely, that compliance with it could mean that any arrangement for post-study access would suffice, as long as it was detailed in the study protocol. Even the sentence "There are no arrangements for post-study access," could arguably be regarded as compliance in that, as long as study participants and ethics review bodies know that there is no provision for post-study access, sufficient compliance with paragraph 14 would have been achieved. Hence, this obligation could be called informational rather than substantial, in which case, it does not satisfy the wider demand for benefit sharing. At first sight, this concern seems to be mitigated through paragraph 33 of the declaration, which reads:

> At the conclusion of the study, patients entered into the study are entitled to . . . share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

This paragraph implies that post-study obligations are a substantial rather than an informational demand for all medical research involving existing patients. However, that still seems to leave healthy volunteers and donors of human biological samples potentially excluded from any post-study benefits, as benefit sharing is only envisaged with patients rather than all participants in medical research. This would seem contrary to the spirit of benefit sharing as understood through the CBD, which aims to reward "resource providers" in particular in order to avoid concerns about exploitation.

Here, one needs to remind oneself of the purpose of benefit sharing for human genetic resources. Formal benefit-sharing frameworks such as the CBD or the Declaration of Helsinki are only required where participants contribute to research but derive no benefits at all. In developed countries, the situation is different. Human sample donors contribute to research and in return have access to increased medical interventions, tailored to local health needs, to achieve and maintain their health. Where this is not the case as in developing countries, other solutions have to be found. In this regard, one could argue that such solutions are only required for vulnerable populations – and this is the approach taken by the Declaration of Helsinki through paragraph 17:

> Medical research involving a disadvantaged or vulnerable population or community is only justified if . . . there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

This means that when ethics review bodies are presented with proposed studies on vulnerable groups which do not fall under the category of "patients," they still need to ensure that the research population or the wider community stand to benefit from the research. Hence, a study protocol which notes that there is no provision for post-study access or alternative benefits would be unethical, according to paragraph 17 (rather than paragraph 14), if it involved vulnerable populations, whether they take part in clinical trials or donate DNA. It is evident that the latest version of the declaration is therefore comprehensive in its benefit-sharing clauses, in providing somewhat intricate frameworks on which arguments in favor of benefit sharing with donors of biological samples can be based. Example cases are described in Boxes 14.4 and 14.5.

Finally, it is important to note that the 2008 Declaration of Helsinki added a benefit to the list of benefits to be shared, which was not hitherto included, namely, feedback. Article 33 requires that:

> At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study.

Before moving onto the next section, it is worth noting that the USA has effectively opted out of the benefit-sharing sections of the Declaration of Helsinki (Kimmelman, Weijer, & Meslin, 2009) by not recognizing the right of vulnerable populations to post-study access to successfully developed interventions or alternative benefits. Table 14.4 summarizes the main challenges in realizing benefit sharing through the Declaration of Helsinki.

The above concludes the section on the established legal sense of benefit sharing as governed through the CBD and the Declaration of Helsinki.

UNESCO Universal Declaration on Bioethics and Human Rights

The UNESCO's Universal Declaration on Bioethics and Human Rights (2005) supports a more ambitious or aspirational approach to benefit sharing, which goes beyond sharing benefits with the contributors to research. The declaration is built on earlier human rights frameworks, of which, the following two are the most important. The Universal Declaration of Human Rights (1948) Article 27(1) notes that (emphasis added)

> [e]veryone has the right freely to participate in the cultural life of the community, to enjoy the arts and *to share in scientific advancement and its benefits*.

Hence, every human being whether they contribute to science, research, and innovation, or not has the *human right* to share in the benefits of scientific advancement. While the Universal Declaration of Human Rights is a nonbinding instrument, the legally binding International Covenant on Economic, Social and Cultural Rights (1966) includes a similar human right. Article 15(b) reads:

> 1. The States Parties to the present Covenant recognize the right of everyone:
> (b) To enjoy the benefits of scientific progress and its applications.

Box 14.4: Nairobi Sex Workers

In 1982, a clinic to investigate the natural history of sexually transmitted diseases was established in Majengo, a slum in Nairobi, Kenya. In 1986, studies focusing on HIV/Aids commenced with particular emphasis on potential resistance to the virus. It appeared that about 5 % of the then 2,000 sex workers did not contract the virus, despite frequent, unprotected sex with HIV-positive men. Since 1998, the main aspiration of the clinic's studies has been the development of an HIV vaccine.

The only way to access the clinic and its health services is by enrolling in its research programs. The Majengo sex workers often have no other income or support, live in small tin shacks, work well into middle-age, and have dozens of clients every day, as payment from each is very low. They belong to an extremely socio-economically disadvantaged group, who would be unable to access health care in any other way. In return for biological samples, the clinic provides health monitoring and health education as well as treatments for all health conditions, irrespective of whether they are sex work-related or not. This includes, since 2005, access to antiretrovirals.

To date, the research has not yielded a vaccine or other treatments. However, considerable progress has been made to understand the immunological protection mechanisms at play. According to the Declaration of Helsinki, the sex workers or their community must benefit from the results of the research. Alternative benefits such as health care can be appropriate. Given that the research began in 1986, this case shows why access to developed drugs is too rigid a mechanism for benefit sharing without the proviso that other benefits might be acceptable.

As in the case of the CBD, the USA is one of the very few countries not to have ratified or acceded to the International Covenant on Economic, Social and Cultural Rights. The only other countries which are not a party to the covenant, except for tiny island states, are Cuba and South Africa. Ratification or accession requires parties to ensure that any provisions from the covenant can be enforced through the domestic legal system.

Before outlining the provisions of the UNESCO's Universal Declaration on Bioethics and Human Rights, it is important to ask the following two questions: What is the relevant justice framework for this type of benefit sharing? And why can this human rights-based approach to benefit sharing be called more ambitious or aspirational than the approach taken by the CBD or the Declaration of Helsinki?

Today, 2.7 billion people live on less than US$2/day. Of these, almost 1 billion are chronically undernourished, 1.1 billion do not have access to safe drinking water, 2.6 billion lack adequate sanitation, and nearly 2 billion have no access to life-saving drugs. People who suffer such massive deprivations are more likely to be susceptible to health risks and enter a vicious cycle of ill health, unemployment, and severe poverty. The above deprivations have little to do with science and

Box 14.5: Indonesian Virus Samples

The World Health Organization (WHO) collects virus samples for distribution to affiliated laboratories in an effort to monitor and assess the risk posed by flu and other infectious diseases, to detect mutations and develop vaccines targeted to specific strains.

In 2006, the Indonesian government decided to withhold avian flu samples from the WHO and its associated vaccine-development laboratories. The argument was that even though Indonesian samples were crucial to the development of vaccines, the results of vaccine research would be unaffordable to its citizens. Indonesia maintained that – in the spirit of the Convention on Biological Diversity – human genetic resources fall under the sovereignty of the nation state and that no global public health measures can enforce access. At this time, Indonesia was the country with the most fatal cases of avian flu.

Appealing to all members of the WHO in 2007, the WHO Director-General Margaret Chan said that cooperation is crucial to combat pandemics and that international public health security is a mutual responsibility. However, she also convened a working group to develop fairer ways for virus sharing.

After several years of negotiations, the WHO working group reached agreement on an alternative framework for virus sharing in April 2011 (WHO Pandemic Influenza Preparedness (or PIP) Framework). This framework is meant to be responsive to the concerns raised by the Indonesian government. The framework was ratified by the WHO at the May 2011 World Health Assembly (WHA) meeting and includes the requirement for two Standardized Material Transfer Agreements (SMTAs). The first SMTA contains terms and conditions which prohibit laboratories that are part of the WHO from making intellectual property claims in relation to the samples shared with them. The second SMTA, among other things, requires those outside of the WHO to commit to at least two conditions, selected from a list of options that includes giving developing countries 10 % of the resulting vaccines and/or antivirals, selling 10 % of these at an affordable price, or granting manufacturing companies within developing countries licenses to produce vaccines/antivirals at affordable royalties or royalty free.

While the PIP Framework addresses some of the concerns with regard to virus sharing, other human biological resources such as DNA and blood are not yet covered by an equivalent, legally binding framework.

innovation. While nanotechnology, for instance, might provide new techniques for water purification, all the necessary means to provide food, water, shelter, and health care to humans around the world are available today. As Amartya Sen pointed out in “Poverty and Famines” (1983), the earth’s resources are sufficient

Table 14.4 Main challenges for benefit sharing: Declaration of Helsinki

Type of benefit sharing	Main challenges
Benefit sharing as justice-in-exchange 	There are almost no examples of good practice for the compliance with post-study obligations in the medical field (except for those cases where comprehensive health care is provided, see Box 4 on Nairobi sex workers)
	Benefit sharing and avoiding undue inducement are ethical obligations that can be difficult to align. However, fear of the latter must not lead to neglecting justice-in-exchange requirements
	The pandemic influenza preparedness (or PIP) framework is to be welcomed, but only covers virus sharing. Similar frameworks need to be established to govern the exchange of other biological specimens of human origin
	Currently, no difference is made between commercial research, basic research, or publicly funded research when it comes to post-study obligations. This topic needs further attention
	The fact that the USA has opted out of the benefit-sharing requirements of the Declaration of Helsinki poses significant ethical issues given the prominence of US researchers conducting clinical trials and other medical studies in developing countries

to feed the world population (as one example of basic human need satisfaction). The main reason for famines is not a shortage of food or the lack of new scientific solutions, but rather the lack of power, sense of entitlement, and resources of the poor. It is thus a matter of distributive justice, the justice that deals with the division of scarce resources among qualifying recipients (see Diagram 14.2) that is at stake. There are enough resources to feed the world, according to Sen, including those in "famine" areas, but some are not regarded as qualifying recipients for such resources.

The main question in distributive justice, namely: *who* deserves *what* from *whom*, has been answered by the human rights framework. Those who live legitimately within a state (*who*) qualify for the receipt of income support at subsistence level plus other services to cover their basic needs (*what*) from the state (*from whom*). The International Covenant on Economic, Social and Cultural Rights from 1966 specifies individual welfare rights, and parties are committed to make these rights claimable through domestic legislation. However, not all states are in a position to respect, protect, and fulfill human rights, as this requires significant resources. It is here that cosmopolitan ethics (Pogge, 2008) as well as international legislation intervenes by adding a demand for international assistance. Hence, the justice framework for sharing the benefits of science, which the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights requires is a distributive justice framework. Resources have to be moved from the affluent or powerful to the poor and vulnerable to secure

everybody's human rights. And it is the UNESCO's Universal Declaration on Bioethics and Human Rights which emphasizes the need for international assistance to do so.

Having clarified the justice framework involved in the more aspirational approach to benefit sharing (international distributive justice), it is also clear why it is more ambitious to demand a sharing of the benefits of science as a *universal human right* rather than a contributor right. To provide equitable access to the results of science to people who are dying because they cannot even get the most basic foods or off-patent drugs will require a mammoth effort, extraordinarily more than achieving compliance with the CBD, which in itself is a difficult task.

The advantage of the UNESCO's Universal Declaration on Bioethics and Human Rights is that it has agreed and described this mammoth commitment as detailed as is possible in a declaration. In the Preamble, it is emphasized that scientific progress can promote the welfare of human beings and that the target is *all of* humanity.

> Recognizing that, based on the freedom of science and research, scientific and technological developments have been, and can be, of great benefit to humankind in increasing, inter alia, life expectancy and improving the quality of life, and emphasizing that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms.

Thus, a belief in scientific progress is combined with the demand to make benefits available to all. In Article 2(f), the importance of international assistance for developing countries is emphasized. The aim is

> to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries

While this is more than previous instruments have included on benefit sharing, the declaration goes further by giving good practice examples through Article 15:

> 1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:
> (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
> (b) access to quality health care;
> (c) provision of new diagnostic and therapeutic modalities or products stemming from research;
> (d) support for health services;
> (e) access to scientific and technological knowledge;
> (f) capacity-building facilities for research purposes;
> (g) other forms of benefit consistent with the principles set out in this Declaration.

Example 15(1)a could be aligned with benefit sharing as practiced under guidance from the CBD or the Declaration of Helsinki. To give special assistance to those who contribute to research recognizes that their efforts need to be rewarded to

Table 14.5 Main challenges for benefit sharing: UNESCO Universal Declaration on Bioethics and Human Rights

Type of benefit sharing	Main challenges
Benefit sharing as distributive justice 	While people are dying from lack of access to the most basic foods or medicines, the human right to sharing the benefits of science is unlikely to be a human right priority among policy-makers. For instance, none of the millennium development goals mentions science and innovation (except indirectly in an appeal to the pharmaceutical industry to provide affordable drugs; Goal 8E)
	While the UNESCO Declaration expands on the International Covenant on Economic, Social and Cultural Rights, it lacks the covenant's legal bite as it is a nonbinding guideline
	Other human rights, such as the right to food, are more easily specified and interpreted. What does it mean to have a human right to share in the benefits of science? The benefits of science range from interactive video war games to tuberculosis drugs
	How will the required international assistance to realize the human right to benefit sharing be mobilized, in particular in a time of financial instability?

avoid exploitation. It is therefore based on justice-in-exchange. Procedural considerations based on a contribution to science are also included in the declaration through recommendations on transnational practices. Article 21(4) requires that when "negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those party to the negotiation." Hence, those who are contributing to science need not only be rewarded for their contribution but should also have a say in the direction, conduct, and dissemination of the research. One might want to term such collaboration as an equitable partnership.

The remaining benefits from Article 15 must be read as human rights, given the spirit of the declaration, and are goals of universal coverage. All human beings should be given access to the benefits as outlined from (b) to (g). Likewise, Article 24 on international cooperation covers universal human rights independent of contribution.

> Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.

At the time of writing, the USA has also withdrawn its financial support from the UNESCO, thereby potentially remaining outside of all leading binding and nonbinding legal instruments involving benefit sharing. The above Table 14.5 summarizes the main challenges in realizing the human right to sharing the benefits of science.

Table 14.6 Tensions between types of benefit sharing

Compensation rights	<- Tensions ->	Human rights
Benefit sharing as justice-in-exchange 	Open access and open source movements can violate compensation rights while furthering human rights	Benefit sharing as distributive justice 
	Patent applications can provide a compliance opportunity for compensation rights, but hinder the protection of human rights	
	Patents can provide financial means to comply with compensation rights, but hinder the protection of human rights	
	Significant bureaucracy necessary to facilitate benefit sharing as compensation could be used to facilitate benefit sharing as a human right	

Conclusion

Two types of benefit sharing can be distinguished. Benefit sharing as governed by the Convention on Biological Diversity and the Declaration of Helsinki aims to reward those who *contribute* to scientific progress, be it by providing resources such as plants or traditional knowledge or by taking part in medical studies. This approach avoids the most blatant exploitation, where somebody's blood sample or traditional knowledge leads to commercial products for the sole benefit of distant others. The aim of this type of benefit sharing is to achieve justice-in-exchange.

The second type of benefit sharing emphasizes that all human beings have a right to access to the benefits of science. The UNESCO's Universal Declaration on Bioethics and Human Rights is the clearest document to promote benefit sharing as a human right given that it does not shy away from the implications for affluent states. "Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries."

Neither type of benefit sharing is easily achieved, and to complicate matters, the two types can come into serious conflict, as outlined in conclusion in Table 14.6.

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