

The Impact of TRIPS and the CBD on Coastal Communities*

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Abstract

This report intends to assess the implications of the Trade-related Aspects of Intellectual Property Rights (TRIPS) and the Convention on Biological Diversity (CBD) for coastal communities' access to, and control over, aquatic biodiversity. To this end, it reviews marine biodiversity, coastal communities' traditional ecological knowledge systems (TEKS) and the biodiversity they have conserved, and the industrial exploitation of marine genetic resources; it then analyzes TRIPS and the CBD as applied to marine biodiversity, and the implications of TRIPS and the CBD for both coastal States and fishing communities' access to marine resources, control over their knowledge, and share of the benefits; lastly, it ends with some proposals for further research and action by the International Collective in Support of Fishworkers (ICSF).

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1. Foreword

Over the past few years, the matter of who controls biodiversity and associated knowledge has been high on the agenda of international development and environmental discourse. Discussions on this issue have been fuelled by both the ever-increasing restrictions on farmers' rights to save seeds and public outrage on a pandemic of biopiracy—the unauthorized appropriation of the plants, knowledge and even the cells of indigenous peoples and local communities the world over. Coastal communities, however, have been largely marginalized from these debates.

This report is the outcome of a one-month desk research on the implications of the international legal framework regulating control over biodiversity, the Convention on Biological Diversity (CBD) and the Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO). The research focuses on the medicinal use of marine biodiversity, both in traditional ecological knowledge systems (TEKS) and Western industry, and in aquaculture.

This research was commissioned by the International Collective in Support of Fishworkers (ICSF).

2. Control over Biodiversity: A Global Issue

It is difficult to overemphasize the importance of biodiversity—the variability within living beings and their relationships to one another and the environment that supports them. Diversity is the key to the organization of living forms. Within a single species, diversity spells change: variability allows the species to combine the adaptation to its current environment with adaptability to new situations. For ecosystems, diversity spells stability: larger numbers of species result in more complex flows of energy, matter and information, which, in turn, tend to make ecosystems more resilient to changes. For life, diversity spells opportunities; and human beings are no exception to this fact.

In Palaeolithic and modern times alike, from Australia to the Americas and the Pacific Islands, species extinctions and ecological havoc have accompanied the waves of expanding human populations [1]. Established rural cultures, however, have relied on their ecosystems' biodiversity for food, healing, shelter and clothing—and they have built their cosmovisions and spirituality around such biodiversity.

Altogether, the intricate interrelationship between nature and culture is called “biocultural diversity”[2]. Biocultural diversity comprehends traditional ecological knowledge systems (TEKS), which are (i) systemic, meaning that any part of the ecosystem is known as it relates to the whole; (ii) local, meaning that they take as a reference the world the

cultures inhabit; and (iii) indissoluble from the culture as a whole, meaning that they cannot be understood on their own.

Since it embeds the strategies of rural peoples to ensure a livelihood out of their environments, biocultural diversity has not only maintained, but sometimes even enriched, biological diversity. The sum of innumerable thousand-year-old interactions among local communities, indigenous peoples and their crops has yielded hundreds of thousands of crop varieties and thousands of domestic animal races. Peoples need only one hundred years to learn how to use the plants of an entirely new area—and how to preserve and look after the most useful ones [1].

By no means does direct reliance on biodiversity belong to the past. The world's poorest rely on biodiversity and TEKS. It is estimated that about 85 per cent of the population of Africa depend on traditional medicine for their health care [3], and 90 per cent of African crops are grown using farm-saved seed [4]. For the rural poor in developing countries, access to biodiversity may be the difference between self-reliance and exclusion. Perhaps even more importantly, the development of TEKS may be the difference between the rural poor's progress and their stagnation.

For industry, biodiversity is a raw material for the pharmaceutical, natural medicine, seed, ornamentals, pesticides, cosmetics and industrial biotechnological sectors. In this context, it is often referred to as *genetic resources*. A 1999 estimate placed the annual commercial value of biodiversity for these sectors at between US\$500–800 bn [5]. Much of this value stems from the development of modern biotechnologies, particularly genetic engineering.¹ Such technologies have dramatically increased the expectations on the use of living organisms and their parts in industrial processes—as commodities, biofactories, or elements of production chains. As industry incorporates living beings into production strategies, it is also ensuring control over them—biodiversity is being privatized. In the United States of America (US) and the European Union (EU), industry has strongly promoted, and obtained, the extension of industrial intellectual property rights (IPRs) to life forms and their parts (see Box 1). Consequently, the scope of patent protection has progressively extended from extracts and substances obtained from living beings, to genes, genetically engineered organisms, and even organisms claimed to be novel. In the process, the differences between invention and discovery have been progressively blurred, and, increasingly, the first to describe something becomes its first owner.

While most of industrial transformation is taking place in developed countries, biodiversity is concentrated in the tropical belts of the planet,

¹Genetic engineering consists in introducing a fragment of deoxyribonucleic acid, DNA, containing genetic information, into an organism, so that the organism acquires a new characteristic.

Box 1
Patents

A patent is a legal claim over an invention that gives the holder exclusive rights to profit from it for a set number of years. It is a privilege granted by the State in exchange for the full disclosure of the invention so that it contributes to society's knowledge. By ensuring the inventors a monopoly on the market for their inventions, patents are supposed to encourage investment in innovation, which, in the end, is to benefit society as a whole. Patents are a form of Intellectual Property Rights—IPRs—designed to protect industrial innovation. Other forms of IPRs include author rights, copyrights, trade secrets, and plant breeders' rights.

To be granted a patent, an applicant must be able to prove:

- *Novelty*: The claim must cover a new idea, not known or used by anyone before.
- *Use*: The patent application must explain what the invention is to be used for and why it is better than existing technologies.
- *Inventiveness*: It must involve an inventive step that is 'non-obvious'.

For a patent to be valid, it must disclose the invention in a way that allows others skilled in the art to reproduce it—otherwise, the patent can be withdrawn.

Permission for public use of the invention is granted by paying the patent holder licence or royalty fees. However, it is the holder's privilege to decide whether or not to provide this permission, and to establish the amount for the royalties. A patent is, therefore, a compromise between the rights and interests of the inventor and those of the public.

Historically, the State developed some mechanisms to protect the public from abusive patent-derived monopolies. Patents were not allowed in strategic sectors such as medicinals, housing, clothing and food. Discoveries, ideas and therapeutic methods were excluded from patent protection. Furthermore, governments introduced *compulsory licensing* rules that could force patent holders to license their patented inventions under given circumstances.

Nevertheless, the history of patent protection is that of a steady growth of the rights of the inventors—who themselves have evolved from a majority of private citizens to a majority of privately-owned corporations lobbying to increase their privileges.

(contd...)

Box 1

Patents (... contd)

Patent holders' rights have grown in three main ways. First, the scope of patent protection has extended as new industries have developed. For example, patent claims by the chemical and pharmaceutical industries led to key decisions in patent offices and courts that extended to substances already existing in nature.

In the late 1970s and throughout the 1980s, another series of court decisions in the US established, for the first time, that bacteria, plants and animals could be patented. ^a Now, even ideas for business are being patented [6].

Second, the value of patents for market protection is being strengthened as IPRs are included in multilateral and bilateral trade and investment agreements. These agreements, in common, oblige the signing parties to recognize the patent holders' rights. TRIPS (see below) is the most important of such multilateral agreements.

Third, industry has strongly lobbied to limit, as much as possible, the conditions under which compulsory licensing can be allowed.

Therefore, unless developing countries react, a bioprospector will soon be able to obtain patents over the use of a marine organism for the treatment of any disease; have his or her property acknowledged in the country where the marine organism has been found; and prevent that country from using any drug obtained from that organism.

It is often argued that IPRs over genetic resources are not relevant for local communities because they cannot be used to prevent the traditional use of such genetic resources. That is, a coastal community using a fish species for curing an ailment would be able to continue to do so even if a company were granted a patent on the active principle in this fish and had its patent enforced in the country of the coastal community. However, patents do shift the control from the local innovators to the patent holder. In this hypothetical case, the patent holder could bar the fishing community from creating a new market for the fish it uses and from creating a niche export market in any country where the patent has been granted; also, it could establish itself as the single purchaser, force an unsustainable fishery to meet its commercial objectives and later shift to new communities or even countries.

^aRespectively through the US Supreme Court decision in *Diamond vs. Chakraborty* (1980), the Patent Office Board of Appeals decision *ex parte Allen* (1987).

and most of it is found in the territories and waters of developing countries. Much of this biodiversity has been created, identified, nurtured or conserved by indigenous peoples and rural communities. Developed countries have had the time, power and resources to extract the most interesting genetic resources from developing countries. Often, they have organized bioprospecting expeditions, which focused on indigenous peoples and local communities, to extract their knowledge over biodiversity—when not their own tissues²—only to ignore or downplay their contribution when filing patents. Such biopiracy is perhaps the clearest exponent of the violence of the privatization of biodiversity.

Developing countries overwhelmingly lack the capital, human resources, technology, knowhow and market access to industrially exploit their biodiversity on their own. Also, the North's IPRs bar them from access to the industrial processes feeding on their biodiversity and to the final products. As a result, many developing countries have chosen to use the biodiversity in their territories as an asset to participate in the benefits arising from their commercialization. Unfortunately, the alternative route of further strengthening and developing TEKS has attracted much less attention.

Currently, there are two international legally binding conventions dealing with control over biodiversity. First to enter in force, the Convention on Biological Diversity (CBD) acknowledges countries' sovereign rights over their biodiversity, and it conditions access to genetic resources to the countries' prior informed consent and the fair and equitable sharing of the benefits arising from the industrial utilization of these resources. Second to enter in force, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) forces all WTO members to establish IPR systems covering all technologies and products, including, to an unprecedented extent, life forms and their parts. TRIPS was proposed and drafted by industry and pushed mainly by the US.

Biocultural diversity, the privatization of life, the impact of patents over TEKS and the implications and contradictions between TRIPS and the CBD, have led to much political debate within indigenous peoples, farmers' organizations, local communities, NGOs, parliaments and governments in Asia, Latin America and the Caribbean, and parts of Africa. Nowhere, though, have coastal communities got involved, and aquatic diversity has virtually been out of these discussions.

²Conceived as a scientific endeavour to study the history of human populations, The Human Genome Diversity Project intended to collect and 'immortalize' human tissue from 722 human populations, including many indigenous peoples from around the world. The project raised ethical concerns because it treated these human populations as objects with no say in the programme implementation and because it gave rise to the patenting of cell lines obtained from some of these groups' tissues.

This report intends to assess the implications of TRIPS and the CBD for coastal communities' access to and control over aquatic biodiversity. To this end, it reviews marine biodiversity, coastal communities' TEKS and the biodiversity they have conserved, and the industrial exploitation of marine genetic resources; it then analyzes TRIPS and the CBD as applied to marine biodiversity, and the implications of TRIPS and the CBD for both coastal States and fishing communities' access to marine resources, control over their knowledge, and share of the benefits; lastly, it ends with some proposals for further research and action by the ICSF.

2.1. Marine biodiversity and the 20,000 new substances

Oceans cover 71 per cent of the earth's surface and account for 90 per cent of the biosphere, showing that biodiversity is not well captured just by species numbers. In 1998, 'only' 200,000 marine animal species, about 20,000 algae and fewer microorganisms had been described; not very impressive figures, compared with over 2 mn animal species and 40,000 plants with flowers inhabiting the continents. Marine species, though, differ much more among each other than their terrestrial equivalents. Only five out of the 33 existing animal phylum are not represented in the marine environment, while 13 of them are exclusively marine. As a result, genetic, biochemical and physiological animal diversity is much larger in the oceans than on land [7].

Another factor that contributes to marine biodiversity is the difference in communities contained at different light, temperature, pressure and food availability conditions. In the open seas, production is highest in the upper layers—the pelagic environment; less than 1 per cent of it reaches the ocean bottom.

Until the middle 1900s, it was believed that the abyssal plates at the sea bottom were inhabited. Modern bathyscaphs have shown that, while its total biomass is very low, benthic fauna in abyssal plates is at least as rich in species, if not more so, as relatively shallow sediments [7].

Marine depths were to deliver another surprise. In 1977, very rich communities were discovered around vents at marine dorsals, at depths over 2,500 m, pressures above 25 atmospheres and temperatures above 100 °C. These communities are built over the symbiotic association of chemosynthetic bacteria and animals. These chemosynthetic bacteria obtain energy out of the oxidation of dihydrogen sulphide instead of photons.

Later on, it was found that chemosynthesis is quite extended in the oceans, and, in fact, it uses the energy of the oxidation of methane from the degradation of organic matter [7]. This challenge of the old belief that all marine production relied on photosynthesis shows to what extent the marine environment remains unknown.

Even the much more accessible pelagic waters have yielded big surprises. For many years, it was thought that most photosynthesis in the oceans was carried on by microscopic eucaryotic³ organisms, phytoplankton. But the world's most abundant known photosynthetic organism, the prokaryote⁴. *Prochlorococcus*, was only discovered in 1988. In fact, a whole new category of plankton, the picophytoplankton, has only been known since 1979. Yet, the newly discovered picophytoplankton accounts for more than 90 per cent of the ocean photosynthesis, which, in turn, accounts for 50 per cent of photosynthesis in the planet [8].

The most diverse marine environments are shallow waters close to the coast. Of the 200,000 marine animals described, 130,000 depend on rocky or coralline substrates; in comparison, 60,000 live in sediments, and only a few thousands are planktonic or pelagic. Coral reefs are the most diverse, complex and productive marine ecosystems. Reefs cover 0.2 per cent of the ocean's area and yet they provide home to one-third of all marine fish species, tens of thousands of other species and about 10 per cent of human fish consumption globally [9].

Diversity in coral reefs is also linked to diversity—and the health—of tropical mangroves and sea grasses, which host the juvenile stages of many fish species [9]. Diversity in coral reefs is not uniform, being highest around Indonesia's waters. Although some developed countries (including Japan, Australia, the US and France, in its overseas territories) hold coral reefs, most are located in developing countries [10].

The oceans still keep many secrets; by doing so, they hold the promise of containing many substances of potential use in different industries. Bioprospectors seek to tap these substances. Before reviewing their activities, though, this report will focus on the first discoverers of what marine (and aquatic) biodiversity may be used for.

2.2. Coastal communities and aquatic biodiversity: knowledge and uses

For many coastal peoples, their culture, identity and TEKS are inextricably linked to aquatic biodiversity. Many of them have developed management systems that, while ensuring the conservation of their food resources, have allowed for the conservation of fish stocks and, it can be argued, their surrounding marine environment. Only recently have such traditional management systems started to receive the attention and credit they deserve.

³Eucaryote cells have an internal membrane that splits cells into two main compartments, the nucleus, which contains most of the cell's genetic material, and the cytoplasm

⁴Prokaryotes are unicellular organisms with no nuclear membrane, like bacteria

Even if—as on land—knowledge on biodiversity has mainly contributed to coastal peoples' food security, they have learned to use it in myriad other ways. One such is its use for healing. For example, the coastal First Peoples of northwestern America (British Columbia) have used marine algae in healing and health care. Rockweed (*Fucus sp*) was used as a burn medicine, and applied to sores, swellings and eyes. Also, it was rubbed on the limbs for strengthening them or to alleviate muscle aches and pains or even paralysis of the legs [11]. Traditional healing practices in the Maldives rely both on terrestrial plant species and many marine species of fish, coral and seaweed [12]. Likewise, northwestern Canada's handcrafting of anchor lines, fishing lines using bull kelp (*Nereocystis luetkeana*), and the weaving of *Eleocharis dulcis* or kuta, in Northern Fiji, illustrate the use of marine (and coastal) diversity in coastal communities' technologies [11, 13]. More directly related to food production, TEKS on aquatic biodiversity have also resulted in the domestication of carp species (see below). The complexity of these systems may be appalling. In Brazil, a study conducted in Conde, a coastal city of State of Bahia, to document the traditional zotherapy knowledge of the Siribinha artisanal fishing community found that this community uses at least 55 animal species as folk medicine, including fish (44 per cent), reptile (17 per cent), crustacean (9 per cent), mammal (7 per cent), bird (5 per cent) echinoderm (5 per cent), annelid (23 per cent) and amphibian (2 per cent) species [14].

Astonishingly little information about coastal communities' TEKS on uses of marine biodiversity other than food is available through the ordinary information channels on indigenous knowledge and genetic resources. This paucity partly reflects a lack of a structured corp of information on these aspects of coastal people's TEKS in English. In 1998, the traditional use of fish and fish products, wastewater, etc, for non-food uses accounted for only 71 of the more than 7,500 innovations and practices compiled by the Honey Bee Database.⁵ [15] This lack of available information has little to do, however, with the actual richness of these thriving TEKS, only 5 per cent of whose wealth is understood by anthropologists—at least, in Southeast Asia [16]. The example of Brazil illustrates the wealth untapped by a single focused study in a single fishing community. Whether these systems can continue to thrive and develop will depend on many factors, including the industrial use of marine biodiversity and the priority societies grant to coastal communities' control over their resources.

⁵The Honey Bee Database has been established by the Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI), to scout, spawn, sustain, disseminate and reward grassroots innovators and experts in traditional, ecological, technological, educational and institutional knowledge developed by local communities and individuals without any outside help. Available at: <http://www.sristi.org/honeybee.htm>.

3. Marine Biodiversity and Industry

Just as it happens with local communities, fisheries for food and reduction purposes are the main form of industrial exploitation of aquatic biodiversity. Marine diversity is increasingly feeding other industries, too. On the one hand, many industries are turning to the sea, expecting that its huge genetic, biochemical and physiologic diversity will contain useful substances—genetic resources. Three factors have contributed to this renewed interest, by increasing aquatic bioprospectors' competitiveness:

1. the dramatic increase of the costs of introducing new substances into the market (from pesticides to drugs);
2. the fact that marine exploration technologies have become cheaper and more sophisticated; and
3. current chemical and genetic screening technologies allowing to quickly analyze small samples of living beings for active substances.

On the other hand, aquaculture is now prospecting wild fish stocks to develop more efficient domestic races.

3.1. Marine biodiversity and the pharmaceutical industry

Coral reefs are by far the most favourite hunting grounds for marine bioprospectors [7]. In a highly dense environment, sessile, soft-bodied marine invertebrates that lack obvious physical defences have to rely on toxic substances to keep at bay predators and competitors for space at bay [17]. Therefore, they are prime candidates to possess bioactive metabolites—potential drugs.

The interest in the chemicals produced by marine invertebrates is not new. In the 1970s, Hoffman-La Roche, by then the world's top pharmaceutical company, had already started a marine exploration operation in Australia, around the Great Barrier Reef. It only lasted two or three years. According to José Fernández Souza-Faro, Chief Executive Officer of PharmaMar, a Spanish company specializing in marine bioprospecting, Hoffman-La Roche's failure was due to the chemical analysis techniques available at the time, which required "30 kg of every marine invertebrate to be able to isolate enough of the compound to elucidate their chemical structure yet have enough to continue to work with" [18]. In 1986, when PharmaMar started its research, mass spectrometry and nuclear magnetic resonance had become so sophisticated that it was possible to work with only 1 to 3 kg of each species. Today, the Australian Institute of Marine Science (AIMS, another leading marine bioprospector), claims that only 2 g of material are required to provide extracts for scanning [19]. Marine bioprospecting

Table 1
**Number of marine chemical structures discovered or refined
in 2000 per type of organisms**

Group of organisms	Chemical structures
Marine Microorganisms	140
Green Algae	8
Brown Algae	10
Red Algae	39
Sponges	316
Coelenterates	193
Bryozoans	7
Molluscs	45
Tunicates (ascidians)	74
Echinoderms	24
Miscellaneous (crustaceans and others)	13

Source: Extracted from Faulkner, J. Marine natural products, *Nat. Prod. Rep.*, 2002, 19: 1–48

is no Herculean task anymore. In 1998, research on the pharmacology of marine chemicals (excluding anticancer research) involved investigators from at least 22 countries [20].⁶

To date, more than 10,000 marine metabolites have been described. A review covering the marine natural products literature for the year 2000 described 869 chemical structures that were either discovered or newly synthesized that year [17]. Table 1 illustrates how bioprospectors cover all the groups of marine organisms. The high number of structures from sponges is in line with the fact that these organisms have provided more marine natural products than any other phylum, due, in part, to their propensity to produce bioactive metabolites.

In contrast, the number of papers reporting the chemistry of echinoderms⁷ is steadily declining. Besides, the historic contribution of bryozoans as a source of marine chemicals is larger than suggested by the table.

The pharmaceutical industry puts this large diversity to work. Research is in progress on antibacterial, anticoagulant, antifungal, antiinflammatory, anthelmintic, antiplatelet, antiprotozoal and antiviral substances with actions on the cardiovascular, endocrine, immune and nervous systems [20]. Nevertheless, marine natural products have been prominently featured in the area of cancer research [17]. Between 1969 and 1995, 63 marine substances were patented as antitumour agents, accounting for half the marine molecules patented for pharmaceutical purposes [21].

⁶Namely, Australia, Belgium, Bolivia, Brazil, Canada, China, France, Germany, India, Italy, Japan, The Netherlands, Norway, New Zealand, Philippines, Russia, Slovenia, Spain, Switzerland, United Kingdom, Uruguay and the United States.

⁷Echinoderms include starfish, sea cucumbers and sea urchins.

The focus on cancer stems from three main reasons:

- important funding by the US National Cancer Institute.
- the fact that the cytotoxins that marine invertebrates produce as a defence from fouling are potential antitumour agents.
- the cancer market is estimated to be US\$16 bn annually and growing.

Consequently, progress in marine cancer research has been noticeable. In 1951, the arabinosyl-nucleosides of the sponge *Tethya crypta* of the Caribbean Sea were discovered. They inspired Ara-C, the first commercialized antitumour agent of marine origin. Today, more than 500 substances with potential antitumour activity [22] have been described; of them, at least 10 highly promising molecules are in pre-clinical studies, eight in clinical studies and two on the market. Table 2 overleaf summarizes available information on the two commercialized and eight currently clinically tested marine antitumour agents.

All in all, marine organisms match terrestrial plants, biotechnologies and synthesis as a source of antitumour agents [22]. Besides, antitumour agents illustrate the particularities of marine drug development—and, by extension, marine product development. Therefore, a closer look at marine bioprospectors, the environmental impact of marine drug development and industry trends, follows.

3.2. Marine bioprospectors

Marine bioprospectors rely mainly on marine invertebrates as a source for biologically active molecules. Although the sampling size for chemical activity scanning has sharply decreased, once an active agent is identified, large amounts continue to be necessary at least for establishing its pharmacology and for pre-clinical trials. However, invertebrates produce these molecules in minuscule quantities: 1 tonne of *Bugula neritina* contains only 0.1–1 g of bryostatin 1 [22]; similarly, it takes 1 tonne of *Ecteinascidia turbinata* to isolate 1 g of ecteinascidin-743 (ET-743) [23]. Human clinical trials involve the use of further amounts of active agents: 5 g, in the case of ET-743. Bioprospectors need to collect large amounts of organisms, obtain them through mariculture, or chemically synthesize the active agents—all of which involve important investments. To the uncertainties inherent in drug development from natural products can be added the high toxicity from active principles, whose full effects may only show up at the last phases of human trials. To face the resulting risks, bioprospectors have a double strategy: on the one hand, they file patents on every aspect of the active agents they discover; on the other hand, they build strategic alliances with the pharmaceutical industry.

Table 2
Antitumorals of marine origin either commercialized or in human clinical trials as of February 2002

Molecule	Company/Main patent holder	Others	Type of Molecule	Organisms of origin	Origin	Availability through	State of development
Cytarabine (derived from spongo-thymidin)			Arabinosyl-nucleoside	<i>Thetya crypta</i> (sponge)	Caribbean seas	Synthesis	Commercialized as Aracytne® (Pharmacia, US) and Cytarbel® (Bellon)
Immunocyanin	Akzo, N.V. (Netherlands) US 5,407,912		Glycoprotein	<i>Megathura crenulata</i> (mollusc)	California	Extraction	Commercialized as Immucothel® (Biosyn Arzneimittel)
Néovastat (AE-941)	Les Laboratories Aeterna Inc., (Québec) Canada) US 5,618,925	Licensed to Grupo Ferrer Internacional (Spain) and Medac GmH (Germany)	Cartilage extract	<i>Squalus acanthias</i> (dogfish shark)	Cosmopolitan	Extraction	Phase III clinical trials
Squalamin	Magaining Pharmaceuticals Inc. (US) US 5,874,597	The Children's Hospital of Pennsylvania NIH, US	Esteroid	<i>Squalus acanthias</i> (dogfish shark)	Cosmopolitan	Chemical synthesis and extraction from shark liver	Phase II human trials

Table 2
... (contid)

Bryostatins	CRI (1) US 4,560,774	Bristol-Myers Squibb (dropped in 1999)	Macrolide (lactone)	<i>Bugula neritina</i> (bryozoan)	Florida and Gulf of California	Sea ranching (CalBioMarine Technologies)	Phase II human clinical trials
Ecteinascidin- 743	Board of Trustees of the University of Illinois US 5,089,273	Licensed to PharmaMar, who will develop it with Johnson	Johnson.	Alkaloid	<i>Ecteinascidia turbinata</i> (ascidia), or endosym- bionts.	Caribbean and Mediterranean seas	Synthesis not yet ready. Mariculture off the Balearic Islands, Tunisia and Cadiz. Caribbean harvesting. Phase II human clinical trials
Dolastatins	CRI US Patent 4,414,205		Peptide	<i>Dolabella auricularia</i> (aplysids or sea hares)	Indian Ocean	Synthesis	Phase I human clinical trials. Two synthetic derivatives are on clinical trials
Didemnin B	Board of Trustees of the University of Illinois (US) US 4,493,796		Peptide	<i>Trididemnum solidum</i> (ascidia)	Caribbean Sea	Harvesting	Found too toxic in Phase II human clinical trials

Table 2
... (contid)

Aplidin	Board of Trustees of the University of Illinois (US) US 5,294,603	Developed by PharmaMar	Peptide	<i>Aplidium albicans</i> (ascidia)	Mediterranean Sea	Synthesis	Phase I human clinical trials
Kahalalide F	PharmaMar (Spain) US 6,274,551		Peptide	<i>Elysia rufescens</i> (Mollusc)	Hawaii	Synthesis in the laboratory	Phase I human clinical trials
KRN7000 (derived from agelasphines)	Kirin Beer Kabushiki Kaisha (Japan) US 5,849,716			<i>Agelas mauritianus</i>	Okinawa	Synthesis	Phase I human clinical trials.
Discodermolide HBOI (2)		University of Pittsburgh National Cancer Institute / Novartis	Polyhydroxylated lactone	<i>Discodermia dissoluta</i> (sponge)	Caribbean Sea	Three synthesis methods in the works	Clinical studies stopped due to low availability.

Source: Based on Biard J. Les antitumoraux d'origine marine: sources, développement et perspectives, *Océanis*, (in press), JF Verbist (1998) La mer contre le cancer, *Biofutur* Vol. 179, pp. 38–39, and other sources. (1)CRI: University of Arizona Cancer Research Institute ; (2) HBOI: Harbour Branch Oceanographic Institution in Fort Pierce, Florida. The table includes only the first patent covering each of the substances.

Following the tradition in the pharmaceutical industry, marine bioprospectors file for, and obtain, patents on the active principles they discover and find a utility for them (see Box 1). These patents often contain the location where the marine invertebrate was obtained—sometimes including even latitude and longitude. In the case of promising substances, bioprospectors do not file a single patent, but rather a battery of patents, each covering new variations of the same active agent⁸, new therapeutic uses, new synthesis steps or processes or new derivatives. With these patents, marine bioprospectors protect their research for improving the availability and utility of their active principles. The higher value of their patent portfolio helps strengthen their potential for establishing alliances with larger pharmaceutical companies.

As seen in Table 3 above, the most successful prospectors for marine antitumour agents identified in the course of this research are US research centres, both public, like the Universities of Illinois and Arizona, and private, like the Florida-based Harbour Branch Oceanographic Institution (HBOI) and the Californian Scripps Institution of Oceanography (SIO). These institutions' work is initially funded by the National Cancer Institution, but they also obtain funds from licensing their technologies to private companies. These companies cover the costs of the antitumour agent development—including those of human clinical trials—in exchange for a privileged position at its commercialization. Some of these deals have involved pharmaceutical giants like Novartis (which licensed the HBOI discodermolide) and Bristol-Myers Squibb (which licensed bryostatins 1). Others involve specialist companies that bear part of the development costs and link up with pharmaceutical giants for commercialization. This is the case with the University of Illinois, which has licensed at least two marine antitumour agents, ET-743 and aplidin, to the Spanish firm PharmaMar (see Box 4). In turn, PharmaMar has raised funds from its parent company, Zeltia, for their development. Finally, after a quite successful Phase II human trials, in 2001, PharmaMar announced that it had reached an agreement with Johnson and Johnson to commercialize ET-743 in the US and Japan. The company expected an income of more than US\$1 bn from this molecule alone [24].

3.3. The environmental impact of marine drug development

In the pharmaceutical industry, the ideal marine active agent can be synthesized in the laboratory immediately after its structure has been elucidated. Industry would only have to care about the environmental

⁸For example, the Arizona State University holds US Patent 4,560,774 covering bryostatins 1 to 3, and US Patent 4,611,066, covering bryostatins 4 to 8.

Table 3
Bioprospecting institutions identified in the course of this research, some of the marine active agents they have patented and the number of patents they hold

Group	Marine active agents	Number of US patents	Comment
Cancer Research Institute of the Arizona State University	Bryostatins, dolastatins, neristatins, dyctiosatin, and cephalostatins	23	Public sector
Harbor Branch Oceanographic Institution (Florida)	Cyclohexadienones, discodermolides, indole alkaloids, misakinolides, cyclic peroxides, discorhabdins, antitumour alkaloids, cyclohexadienones	60	Private foundation with strong links to public universities
PharmaMar	Crambescidins, kalahide F, sesbanimide, MT 332, epidioxymanadic acids A and B, mycaperoxides (the company claims it has patent applications on 28 innovations)	6 (the company claims 222)	A subsidiary of Zeltia, a Spanish chemical group.
University of Illinois	Ecteinascidins, didemnins, spisulosins	7	Public sector

impact of its sampling activities for chemical screening and of that of the harvesting of the specimens necessary to isolate and characterize the active principle. Industry would then be able to obtain the increasing amounts of active agent necessary to undertake pre-clinical studies, human clinical trials and, eventually, commercialization, free of any tie to the oceans. Industry also prefers synthesis because it can then obtain derivatives with improved action or fewer negative side effects.

However, most marine active agents are highly complex and prove very difficult—and expensive—to synthesize. In the meantime, pre-clinical and human clinical studies rely on marine invertebrates. Some companies continue to depend on wild populations to feed their studies. Others have invested in cultivating marine invertebrates as a way to ensure and increase their supply. On the whole, the environmental impact of the development of marine drugs differs with the biology

of the exploited species and the concentration and complexity of their active agents.

As already seen, the direct environmental impact of the collection of marine species for chemical screening is now much lower than it was 30 years ago. The higher efficiency and speed of current screening technologies may, in turn, help quicker identify more potentially interesting species. The environmental impact of aggressive scanning may simply be replaced by that of the exploitation of more species.

When the concentration of the active principles is very low, even initial collection efforts may prove unsustainable. An example is dolastatin 10, which was isolated in very low yield (0.1–1 g per tone) from the sea hare *Dolabella auricularia* from the Indian Ocean. Such large (1,600 kg) collections were made that the project was criticized as an assault on biodiversity conservation [17]. Dolastatin 10 was subsequently synthesized and the molecule followed its way through the clinical evaluation process.

The sea squirt, *Ecteinascidia turbinata*, delivers its active agent, ET-743, at the same concentrations as *D. auricularia*. However, *E. turbinata* is a fast-growing species, and, in principle, it is possible to obtain three crops a year from the mangrove swamps of the Caribbean. This is only possible, though, if collectors are careful and the mangrove roots the species colonizes are left untouched—which is not always the case [23].

ET-743 is also an example of the possibilities of invertebrate mariculture. Using a technology developed by CalBioMarine Technologies, PharmaMar has cultivated it in the Atlantic Ocean and the Mediterranean Sea. PharmaMar claims that, in the year 2000, it obtained 96 tonnes of *Ecteinascidia turbinata* from its aquaculture and mariculture facilities. CalBioMarine Technologies has also successfully cultivated *Bugula neritina*, the bryozoan producing bryostatin 1 [22].

However, mariculture is not an ideal solution, either for the environment, or for the pharmaceutical industry. An environmental impact assessment of the introduction of these aquaculture activities should be conducted, especially when the species is to be cultivated outside its natural distribution range or living conditions. In addition, successful mariculture does not necessarily put an end to the harvesting of natural ecosystem—at least, PharmaMar has not abandoned the collection of *E. turbinata* from the Caribbean Sea [25].

For industry, mariculture is only a mid-term solution for the problem of supply of active agent: it can help through the drug development process, but it cannot produce the amounts of active agent required for large-scale commercialization. In order to feed the estimated market of 2.5 kg of ET-743 a year, PharmaMar would need to grow 2,500 tonnes of *E. turbinata*! Therefore, in parallel to its mariculture projects, the Spanish firm has developed a synthesis process for ET-743 [18]. In fact, some

experts think that reliance on mariculture is the main reason behind Bristol-Myers Squibb dropping its exclusive licence on bryostatin 1 [22].

3.4. Coastal communities and marine bioprospecting

To find new active agents, marine bioprospectors prefer screening marine organisms, rather than coastal communities' knowledge. In turn, bioprospectors regard highly local knowledge of biodiversity distribution; indeed, their safety relies on local fishermen's knowledge of tides and ability to avoid danger [26].

Bioprospectors rely on professional scuba divers, rather than local fishing communities for harvesting invertebrates. The National Cancer Institute has used the Coral Reef Research Foundation for many years. The main reason for this is that samples are taken according to established protocols and have to be frozen immediately. Fishing communities can only harvest these resources after extensive training, but few—if any—programmes for such training have been implemented [26].

In contrast, industrial fishing boats are in a much better position to collect interesting invertebrates—at the cost of a far greater environmental impact.

When the shift towards mariculture production and chemical synthesis of marine active agents are seen in the light of these limitations, the scope for coastal communities' direct participation in sustainable fisheries of active agent-producing organisms seems quite limited. The first real test of large-scale harvesting of a marine invertebrate has come from the commercialization, by the cosmetics firm Estée Lauder, of a partially purified extract of *Pseudopterogorgia elisabethae*, a gorgonian from the Caribbean Sea. This extract contains pseudopterogens, which are antiinflammatory agents. According to John Faulkner of the Scripps Institution of Oceanography of the University of California, more than 4.5 tonnes of gorgonians had been extracted by the year 2000. The gorgonians, which occur between 13 and 23 m depth, are pruned by hand along an approximately 96-km length of the Bahamas coastline. Diving is limited to about 18 m, so that the deep-water specimens provide a reservoir of breeding stock. Re-growth occurs in about one-and-a-half years. Researchers believe that the harvesting of *P. elisabethae* populations can be sustainable, if managed carefully.

3.5. Trends for the future

Industry experience in marine antitumour agent development shows that (i) the oceans are a valuable source of antitumour agents; (ii) these agents hold pharmacological properties and action mechanisms

similar to usual antitumour substances; and (iii) the main obstacle to their development is the difficulty in obtaining the products in enough quantities for the industrial production of the future drug [22]. Analysts hope that two emerging trends may help overcome these barriers. First, synthetic methods are constantly improving so that even complex molecules or, preferably, simpler analogues based on marine metabolites, can be synthesized on industrially useful scales. Second, there is a growing body of evidence to indicate that many of the active agents present in invertebrates, in reality, come from their diet or from bacterial symbionts or epybionts.

If the latter were the case, it would be possible, in principle, to obtain the active agents from the in vitro culture of either the invertebrates' cells and their bacterial symbionts, or the epybionts. To date, efforts to cultivate sponges' cells have failed as they become inactive after a certain number of divisions [23]. Marine bacteria are even more difficult to grow. Ultimately, the hopes of marine bioprospectors lie in current molecular genetics techniques. These could allow identification of the bacterial genes involved in the metabolic pathway producing the active agents. Then, in theory, it would be possible to transfer the genes involved in this metabolic pathway to familiar bacteria such as *Escherichia coli*, which is already used industrially to produce, among other things, human insulin. Already, advances in marine biotechnology have resulted in an increase in the number of papers reporting studies on microorganisms' marine natural products. Marine drug production may be slowly shifting from the oceans to the tubes; in the process, the prospects of coastal communities participating in sustainable fisheries of active agent-producing organisms are fading.

4. Aquaculture

Between 1987 and 1997, the global production of farmed fish, shellfish and crustaceans (collectively called 'fish') more than doubled in weight and value, as did their contribution to world fish supplies [9].⁹ Aquaculture embraces a range of practices with different histories and implications for aquatic biodiversity. In low-external input aquaculture (also called extensive aquaculture), raised animals are protected from predators and competitors; in semi-intensive aquaculture, their food supply is enhanced; in intensive aquaculture, the farmer provides them all their nutritional requirements, which allows generating high fish densities. Aquaculture uses more than 220 species of fish. Table 4 compiles the world's aquaculture production in 1998.

⁹Much of the general information on aquaculture in this report is extracted from the excellent article by Naylor *et al.*

The raising of carp within complex agricultural rice systems in China is perhaps as old as rice culture itself; rice farmers in Kerala, India, have, for centuries, managed a polyculture system based on rotational cultivation of rice and shrimp, called *chemmeenkettu*; the Japanese learned to favour the growing of seaweed for their diet 300 years ago. The fruit of farmers' ingenuity and inventiveness in biodiversity management, such low-external input aquacultural systems do not compete with other uses of the aquatic environment, but rather complement them by helping to close nutrient cycles [27].

Some sources report, unfortunately, that in China and other parts of Asia, many small-scale farming operations are intensifying as land and water resources become increasingly scarce and valuable [9]. In contrast with extensive systems, intensive aquacultural systems have a much shorter history: they, are in fact, the result of the "Blue Revolution", that is, the reproduction of the "Green Revolution" production model in aquaculture.

Consequently, and just like their terrestrial counterparts, intensive systems require the use and management of inputs, generate large amounts of waste products and are more susceptible to the spread of pathogens.

The Blue Revolution incorporated new, high-value and often carnivorous species into aquaculture, like crustaceans, salmon and marine fish. Nevertheless, it has also targeted extensive aquacultural systems, mainly through the introduction of improved tilapia—the first case of targeted efforts to genetically improve an aquacultured species.

As seen in Table 4 overleaf, the bulk of aquacultural production is made up by freshwater fish, molluscs and aquatic plants [31]—produced mainly under extensive conditions. In terms of value, the most important farmed groups are freshwater fish, crustaceans and molluscs. In general, the Blue Revolution carnivorous species fetch the highest prices. Of course, production costs for intensive aquaculture are higher too—feed accounts for half of them.

Chinese farmers probably started to domesticate carp thousands of years ago, as they domesticated rice. The domestication of carp is the exception rather than the norm in aquaculture, which has relied on fish stocks from a narrow centre of origin, with subsequent inbreeding causing impaired genetic performance. Tilapia is a good illustration.

According to Roger Pullin, a former staff of the International Centre for Aquatic Living Resources Management (ICLARM), in 1962, some tilapia specimens were collected from the open waters in Egypt and shipped to Japan. In 1965, some of their descendants were shipped to Thailand and they produced a strain that has since then been widely farmed. A few fish of this strain were introduced in the Philippines in 1972 and their descendants have since been farmed there [29].

Table 4
Total aquacultural production in 1998

Species group	Total production Mt	Total value MUS\$	Average price 1000US\$/t	Main farming farming method
Freshwater fish	17355	19737	1.137	Extensive and intensifying
Molluscs	9143	8479	0.927	Extensive
Aquatic plants	8568	5377	0.628	Extensive
Diadromus fish	1909	5907	3.094	Intensive
Crustaceans	1564	9234	5.904	Intensive
Marine fish	781	3396	4.348	Intensive
Other aquatic animals	111	330	2.973	Several

Source: FAO State of the world fisheries and aquaculture 2000

Despite Filipino farmers' selection efforts, in 1989, their tilapia aquaculture turned out to be less efficient than new founder stocks collected from the wild in Egypt. To solve this problem, ICLARM launched the Genetic Improvement of Farm Tilapia (GIFT) project to develop genetic resources for tilapia, which resulted in the creation of the "super-tilapia" using wild populations from Egypt, Senegal, Ghana and Kenya [30].

Although modern breeding in aquaculture is a recent phenomenon and the majority of farm-raised aquatic animals and plants are very similar to their wild forms, selective breeding programmes have already yielded significant and consistent gains of 5–20 per cent per generation in species of, *inter alia*, Atlantic salmon, catfish and tilapia [31]. In fact, the optimistic prospects for the future contribution of aquaculture to the world's food security rely on productivity increases resulting from selective breeding. Accordingly, interest in selective breeding programmes is increasing worldwide: in Asia and Africa, they are envisaged for shrimp, tilapia, common carp and *rohu*; in the Mediterranean region, their application to marine fishes such as sea bass and sea bream has been identified as a top priority [32]. Like the GIFT project, the success of these and other programmes will depend on their capacity to access those cultivated species' genetic diversity in the wild (in farmers' ponds, in the case of carp). However, such access is problematic as aquatic biodiversity, especially in freshwaters, is threatened by human activities, further eroded by aquaculture itself.

4.1. The dwindling base for aquaculture

Marine fish genetic diversity is still not well understood, and there is no agreement on the main factors that contribute to it. In contrast, it is commonly accepted that freshwater fish populations, which have been isolated from others for long periods of time, have adapted to their environments through particular genetic combinations. Freshwater fish diversity is embodied in those particular genetic combinations.

Fish genetic diversity is eroded, among other factors, by fishing—including the fishing down of the aquatic web—habitat destruction, pollution, the introduction of alien species and restocking with alien populations. Human ability to alter freshwater environments—through dam construction, water transfers between different hydrographical basins, the modification of rivers' paths, etc—is the most serious threat. At the species level, freshwater fish are the most threatened of all species groups that are widely exploited by humans. Erosion is impressive: more than 300 stocks of native Pacific salmonids are at risk of extinction in the Pacific northwest and even the US does not have enough resources to conserve them all [33]; the introduction of the Nile Perch in Lake Victoria led to the loss of 200–300 fish species. Unfortunately, the list could go on and on.

Aquacultural activities have also contributed to the erosion of fish genetic diversity, at many different levels:

- Since it is impossible to avoid the escape of aquacultured species into the environment, aquaculture has an impact on biodiversity, when it involves the introduction of aliens into an ecosystem. Tilapia is a case in point. Introduced in more than 85 countries, the species is highly carnivorous and can expand at the expense of less aggressive indigenous fish. In fact, it has already led to the depletion of a fish indigenous to Costa Rica, the *guapeta* [34].
- The large-scale escape of cultured populations into freshwater environments may lead to the introgression of the cultivated germplasm into the genetic structure of the wild populations. In the Magagudavic River, Canada, 1995 estimates indicated that 90 per cent of the salmon caught was of farmed origin.
- Newly introduced populations have sometimes brought parasites or viruses with them that have, in turn, affected wild biodiversity [9]. Many native populations of Atlantic salmon in Norway are threatened with extinction from a parasite introduced through genetically resistant salmon populations from the Baltic Sea. More recently, the white spot virus that caused catastrophic losses in shrimp farms across Asia has brought high mortalities into Texas shrimp farms and may cause mortality of wild crustaceans [9].
- Fishing for seed to stock aquacultural operations may have large

consequences for wild fisheries. An example is the farming of milkfish in the Philippines. Milkfish constitute only 15 per cent of total finfish fry collected inshore by seine nets—the remaining 85 per cent are discarded and left to die on the beach. In India and Bangladesh, up to 160 fish and shrimp fry are discarded for every fry of the giant tiger shrimp collected to stock ship ponds [9].

- Aquaculture also has a direct impact on fish diversity because it contaminates the water and involves habitat destruction—especially shrimp ponds in mangrove areas—and, more indirectly, because it promotes the use of low-value fish species as feed, as exemplified by Thai trash fisheries.

4.2. Poor knowledge

Although the number of farmed species reported to the Food and Agriculture Organization of the United Nations (FAO) is increasing, there is a vast amount of information on genetically differentiated strains, races and varieties that is not well-reported, hampering both conservation efforts and selective breeding programmes.

4.3. Initiatives

The realization of the erosion of fish genetic diversity has resulted in efforts to reverse these trends and promote the in situ conservation of fish aquatic diversity through a variety of initiatives, projects, regulations and policies on coastal areas development, alien species introduction, re-stocking, genetic conservation and quarantine periods. Unfortunately these regulations and policies are not always adequate and/or enforced, particularly—but by no means only—in developing countries [35]. Meanwhile, industry, the public sector and indigenous peoples have launched programmes for the ex situ conservation of fish genetic resources, by building gene banks of cryopreserved fish sperm. Such gene banks can then be used to preserve diversity and as broodstock for breeding programmes.

The World Fisheries Trust (WFT), a Canadian non-for-profit organization, has assisted the Shuswap First Nation of Canada in preserving the dwindling genetic variability in several species and stocks of Pacific salmon in their territory in southwestern British Columbia. In Brazil, the WFT is involved in a gene banking programme that aims to collect and use genetic material from indigenous migratory species. Brazilian fish farmers are shifting from the culture of alien species (like Chinese carp and tilapia) to these migratory species, which command a much higher price. For many of these species, wild broodstock are becoming harder and harder to find [36].

After the success of the GIFT project, in 1993 ICLARM set up the International Network on Genetics in Aquaculture (INGA), which supports its member countries through strengthening their research capacities, supporting their national breeding projects, and promoting germplasm exchange. Currently, 13 Asian and African countries have joined this initiative [37]. FishBase (<http://www.fishbase.org>) is another ICLARM tool to document available information on fish genetic diversity and its use in aquaculture.

The expectations on long-term productivity increases derived from the use of fish genetic resources have also resulted in the extension of property rights over them—in a process that parallels that of plant genetic resources for agriculture. As a member of the Consultative Group on International Agricultural Research (CGIAR), ICLARM has endorsed the CGIAR's IPR policy. The CGIAR is promoting the transfer of intensified production systems for the benefit of the poor. Its IPR policy is highly controversial. On the one hand, it is designed to prevent others from obtaining IPRs on genetic resources as collected and provided by gene banks. On the other hand, it allows for the “defensive patenting” of inhouse developed technologies and products. No matter whether this “defensive patenting” intends to ensure that the CGIAR inventions will not be slightly modified and patented by somebody else, or seeks providing the group with bargaining chips to negotiate the transfer of technologies from the private sector, it legitimates the patenting of genetic resources.

The trend towards the patenting of fish genetic resources, and even the patenting of new breeds of fish, is accelerating as the aquaculture industry applies biotechnology shortcuts—including hybridization, sex manipulation, polyploidy and genetic engineering—which are more amenable to patenting than selective breeding.

5. Other Industries

The pharmaceutical and aquacultural industries are not the only prospectors of marine biodiversity. Although a detailed description of these other branches is beyond the scope of this report, a brief introduction to some of them, organized as per the marine ecosystems they exploit, follows.

Phytoplankton is grown industrially to produce raw biomass and value-added food and feed supplements, such as proteins, eicosapentaenoic acid and betacarotene (respectively obtained from *Spirulina*, *Nannochloropsis* and *Dunaliella*). In some developing countries, the expansion of shrimp farming has led to microalgae cultivation to feed larvae. Phytoplankton is also used for environmental cleansing. Besides its current uses, phytoplankton holds a large potential source

of genes and substances, which is already attracting the pharmaceutical industry. In 1998, the Department of Biotechnology of the Tokyo University of Agriculture and Technology claimed that the lines in its phytoplankton collection could produce a range of substances—from plant growth regulators (of potential interest to the agrogenetic industry) to new antiviral and antibiotic molecules (attractive to the pharmaceutical industry) to ultraviolet filters, which might feed the cosmetic and personal care industry. According to the Department's Tadashi Matsunaga, most of the samples of this collection were isolated in the coasts of several regions in Asia and Micronesia [38]. As already mentioned, phytoplankton is now also attracting the pharmaceutical industry.

The microorganisms living in deep-sea vents, the bacteria digesting whale skeletons in the bed of the Arctic Ocean and the bacteria looming in highly saline lagoons share the ability to survive in conditions that, for most of the rest of organisms we know, and certainly for human beings, are extreme conditions. Consequently, they are referred to as “extremophiles”. A branch of the biotechnology industry is specialized in identifying extremophile microorganisms, cloning their genetic material and producing its enzymes¹⁰ in laboratory bacteria. These enzymes can be then used in industrial processes at high temperatures or under high pressures—depending on the organism they come from. They can also be genetically modified to fit a particular process even better. Some companies working to develop extreme enzymes out of extremophiles are Diversa, Novo Nordisk, Genencor, Amgen and Recombinant BioCatalysis.

As a last example, another important research line is looking for antifouling molecules in the same sessile invertebrates where the pharmaceutical industry is looking for antitumour agents. Non-pollutant antifouling molecules of marine origin could save annual losses of more than US\$1.5 bn [39].

6. The International Legal Frame of Control over Marine Biodiversity

The international community deals with control over marine biodiversity mainly through three Conventions that have become international law: The United Nations Convention on the Law of the Sea (UNCLOS), the Convention on Biological Diversity (CBD) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO).

¹⁰An enzyme is a protein that catalyzes chemical reactions within an organism's metabolism.

6.1. The United Nations Convention on the Law of the Sea (UNCLOS)

Negotiated between 1973 and 1982 and entered into force in November 1994, UNCLOS is the international convention governing the world's oceans. UNCLOS is relevant to control over biodiversity in three ways:

- it establishes the rights and obligations of coastal States on the marine areas surrounding them, and the rights and obligations of other States on those waters;
- it sets the conditions to conduct marine research; and
- it forces countries to give access to “surpluses”.

UNCLOS grants coastal States full sovereignty over their territorial sea—a belt of sea adjacent to the countries' coast, no wider than 12 nautical miles (UNCLOS Art.2). UNCLOS also establishes the Exclusive Economic Zone (EEZ), a belt of sea adjacent to the countries' coast, no wider than 200 nautical miles, where the coastal State has “sovereign rights for the purpose of exploring and exploiting, conserving and managing the natural resources, whether living or non-living”(UNCLOS Art. 56). Beyond countries' EEZs are the high seas, to which all countries have free access rights. Therefore, UNCLOS both grants and limits the extension of coastal countries' rights into the seas and their inhabitants. The CBD would later extend sovereignty to cover the biodiversity—and the genetic resources—in territorial seas and EEZs.

UNCLOS sets some obligations on scientific marine research. It grants coastal States the exclusive right to regulate, authorize and conduct marine scientific research in their territorial sea—just as they have in their land territories (UNCLOS Art.245). In the EEZs, these rights are modulated by the obligation, in normal circumstances, to grant foreigners consent for marine scientific research (UNCLOS Art.246). These foreigners are subject to a number of obligations, including providing information on their research activities, accepting the coastal State's participation in research programmes, and providing access for the coastal State to all data and samples derived from the marine scientific research project (UNCLOS Art.249). Such provisions oblige any company wishing to carry on bioprospecting agreements to inform coastal countries of its purpose to do so. This is a first—and strong—step towards the concept of “previous informed consent” developed under the CBD.

UNCLOS obliges coastal States to determine their capacity to harvest the living resources of the EEZ and give other States access to the surplus of the allowable catch (UNCLOS Art.62).

6.2. Convention on Biological Diversity (CBD)

The Convention on Biological Diversity (CBD or the Convention) was born out of a bundle of common concerns and conflicting interests, including:

- the growing recognition that biological diversity is a global asset of tremendous value to present and future generations;
- the unprecedented threats to species and ecosystems;
- the rise of biotechnology, genetic engineering in particular, as the new area of industrial growth for the North;
- the spectacular increase of IPR claims on developed countries' "inventions" building on genetic resources and associated knowledge from developing countries;
- increasing pressures on developing countries to have them accept such IPRs; and
- the then existing regime of free access to biodiversity "as found in nature", which prevented developing countries from:
 - * protecting their peoples from the appropriation of their biodiversity and associated knowledge
 - * avoiding the privatization of this diversity by denying access to it; and
 - * participating in the benefits arising out of the use of the biodiversity hosted in their territories.

The CBD is a compromise on these common concerns and conflicting interests, achieved by an Intergovernmental Negotiating Committee, and adopted on 22 May 1991 in Nairobi. The Convention was opened for signature at the 1992 United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro. The CBD came into force and became international law on 29 December 1993, after it had been ratified by 30 countries. By March 2002, it had been signed by 168 countries and ratified by 154.

The Convention (see Box 2) is a framework agreement that gives goals and policies. The Conference of the Parties (COP) is responsible of further implementing the CBD through its meetings, special meetings on specific issues, and the promotion of protocols.

The compromise attained by the CBD is very well summarized by its objectives, which are contained in Article 1:

"The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of

relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.” (CBD, Article 1)

The CBD acknowledges three types of rights over genetic resources and technologies. For the first time, the CBD establishes that States have **sovereign rights** over their biodiversity and the genetic resources it contains (CBD Art.3). Simultaneously, the Convention acknowledges IPRs on the technologies and products derived from the (industrial) use of those genetic resources (CBD Art.16).

Therefore, the States that are parties to the CBD must abide by national sovereignty and IPRs. The CBD also acknowledges the rights of “indigenous and local communities relevant for the conservation and sustainable use of biological diversity”(CBD Art. 8(j)).

However, the rights of these “indigenous and local communities” are not explicitly recognized in the text of the CBD; furthermore, their enforcement is subordinated to national legislation. Consequently, parties are not obliged to acknowledge such rights to any meaningful extent—unless the Convention develops a Protocol or an agreed interpretation of the Parties’ obligations on this regard.

The Convention is based on an intimate link between biodiversity conservation and sustainable use. Although the term ‘sustainable use’ is open to many interpretations, its use in the Convention is biased towards industrial use and biotechnology. This is so because developing countries’ claim for compensation for industry’s profits upon their genetic resources, as well as developed countries’ interest to ensure access to those genetic resources, underpin the Convention. The potential cash flows and technology transfers resulting from the development of a market on developing countries’ genetic resources have since dominated the CBD agenda. As a result, as CBD provisions are being developed for implementation, countries are urged to make transparent, reliable and simple access mechanisms, which are convenient for bioprospectors. Countries are also urged to involve their indigenous and local communities in national access legislations. To facilitate this involvement, countries are encouraged to provide their indigenous and local communities with training on the negotiating of agreements and taxonomy.¹¹

What is even worse, the rights of indigenous and local communities are being assimilated to IPRs. The CBD was born as an effort to pay justice to indigenous peoples and local communities suffering from unbridled biopiracy.

¹¹See, for example, the recommendations adopted by the Ad Hoc Open-Ended Working Group On Access and Benefit-Sharing (UNEP/CBD/COP/6/31 October 2001). In spite of Article 10(c), TEKS are perceived more as bargaining opportunities to establish access and benefit sharing agreements with industry than as objects of conservation and development of their own.

Box 2

The CBD in a nut-shell

The first operative provisions of the CBD (Art 6 to 14) cover the obligations of the States that are parties to the Convention (parties) to establish the foundations for the conservation and sustainable development of their biodiversity. Such obligations include developing national strategies for the conservation and sustainable use of biodiversity; identifying, monitoring and establishing databases on the key components of their biodiversity; implementing *in situ* conservation mechanisms; implementing supportive *ex situ* conservation mechanisms, preferably in the countries of origin; promoting the sustainable use of biodiversity—including its customary use; incentivizing biodiversity conservation and sustainable use; encouraging research and training; promoting public education and awareness, and conducting environmental impact assessments; and minimizing adverse impacts of its projects, programmes and policies.

The rights of indigenous and local communities are implicit in this first part of the Convention, in the provisions of Article 8(j), which reads as follows:

Art 8. *In situ* conservation

Each Contracting Party shall, as far as possible and as appropriate:

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

Furthermore, Article 10(c) requires parties to “protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements”.

The obligations under these first operative provisions should result in a real improvement of the conservation and sustainable use of biodiversity, the first two objectives of the Convention. They provide the basis to attain the rest of the CBD objectives, promoting access to genetic resources and technologies, which are addressed in the provisions under Articles 15 to 19.

(contd...)

Box 2: The CBD in a nutshell (... contd)

Countries are obliged to establish mechanisms to grant access to their genetic resources and biodiversity. This access is conditioned to the Prior Informed Consent (PIC) from the country providing the genetic resources, and it is subject to the fair and equitable sharing of the benefits. The conditions for access and benefit sharing (ABS) are established in a contract between industry and the State—Art. 8(j) only recommends the participation of “indigenous and local communities” in such contracts, which is subject to national legislation.

The provisions on access to genetic resources are complemented by others on the transfer of the technologies developed. Such technology transfer is to acknowledge IPRs on these technologies; in this sense, the CBD text promotes, rather than prevents, the adoption of IPR systems on biodiversity. However, the Convention includes a provision requesting countries to co-operate to ensure that IPRs are “supportive of and do not run counter to [the CBD] objectives” (CBD Art.16.5). This attempt at ensuring that the CBD takes preference over private IPRs upset the United States of America so much that it became one of the reasons why it never ratified the Convention [40].

The Convention also requests countries to exchange information on biodiversity conservation and sustainable use from all publicly available sources, including information on indigenous and local communities, and to undertake technical and scientific co-operation—through which developed countries support developing countries’ capacities. In particular, the Convention encourages “the effective participation in biotechnological research activities” by countries providing genetic resources, and stresses the need to share the benefits arising from biotechnologies with those countries, taking into account the adverse effects that living modified organisms resulting from biotechnology may have on biodiversity.

The last part of the CBD text (Articles 33 to 42) contains the CBD functioning provisions, including the establishment of a funding mechanism, under the guidance of the COP, to help developing countries meet the full incremental costs to them of implementing measures which fulfill the obligations of the CBD; the relationship with other international conventions—including consistency with UNCLOS; the COP; the Secretariat; the Subsidiary Body on Scientific, Technical and Technological Advice, made up of competent national representatives; reports; dispute settlement, and the means for the modification of, and adherence to, the Convention.

Many indigenous peoples, local communities and groups supporting them hope that Article 8(j) will allow the definition of a clear set of indigenous peoples’ and local communities’ rights, based on their own needs. Such rights would empower indigenous peoples and local communities to ensure the conservation and sustainable development of their TEKS.

They would also allow these peoples and communities to participate in the benefits arising from the sharing of their knowledge. Unfortunately, currently the CBD is even taking as a reference the work that the World Intellectual Property Organization (WIPO) is developing to incorporate TEKS into the IPR umbrella, in order to accommodate the CBD to the TRIPS setup (see later)¹². This, in spite of WIPO's mandate to promote the IPR systems that allowed biopiracy in the first place.

If these trends are left unchecked, indigenous and local communities may find, at the end, that the only gain they have accrued from the CBD is a small fraction of the benefits that others are gaining from using their biodiversity (as illustrated in Table 5 overleaf); a far cry from control over their resources, knowledge systems and livelihoods that could emerge from the conservation and sustainable development of cultural biodiversity and the TEKS it feeds.

6.3. Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) came into force on 1 January 1995, as an outcome of the negotiations of the Uruguay Round of the General Agreement of Trade and Tariffs (GATT).¹³

Some of the main features of TRIPS follow:

- Setting minimum standards.
TRIPS forces countries that are members of the WTO to fulfill minimum standards for protection in the areas of copyright, trademarks, geographical indications, industrial designs, patents, layout designs of integrated circuits and undisclosed information.
- Equal treatment for all inventors and all exporters.
The National Treatment clause requires WTO members to treat the nationals of all other member countries exactly the way that they treat their own nationals; the Most-Favoured-Nation (MFN) clause requires them to treat the exporters of all other member countries

¹²See Recommendation 2/6 on the assessment of the effectiveness of existing subnational, national and international instruments, particularly intellectual property rights instruments, that may have implications for the protection of the knowledge, innovations and practices of indigenous and local communities, in the Report of the Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention on Biological Diversity on the Work of Its Second Meeting (UNEP/CBD/COP/6/7).

¹³This analysis feeds in part on the assessment of the TRIPS Agreement by the Genetic Resources Action International GRAIN in *The International Context of the Sui Generis Rights Debate* in *Signposts to Sui Generis Rights: resource materials from the international seminar on sui generis rights* co-organized by the Thai Network on Community Rights and Biodiversity (BIOTHAI) and GRAIN, Bangkok, 1-6 December 1997, pp. 9-27.

Table 5
The distribution of the benefits rising from the use of TEK systems by the herbals sector

Plant Name & Use	Origin	US Price*	Price In Country Of Origin**	Value Exported
<i>Azadirachta indica</i> (Neem) Pesticide	India, Southeast Africa	\$524	Ex Factory Price: US \$0.40 per kg for filtered, unrefined oil; up to \$69 for medicinal quality oil (India)	87 per cent - 99 per cent (Indian oil producer: 0.08 per cent - 13 per cent)
<i>Centella asiatica</i> (Gotu Kola), Pennywort Stress, depression	India, Asia	\$437	Herbalist Store Price: US \$0.75 - 1.25 (leaves, Los Baños, Philippines)	> 99 per cent (Herbalist, also often a grower: 0.23 per cent)
<i>Harpagophytum procumbens</i> (Devils Claw) Arthritis	Namibia, South Africa, Botswana	\$702	Collector Price: \$0.16 - 0.66 (Namibia) Export Price: \$2.30 - \$3.28 (Namibia)	99.21 per cent (collector: 0.06 per cent)
<i>Lingustizom porteri</i> (Osha)	US - Native American	\$1384	Contract Price for Indigenous Farmers: \$0.44 (dry plant material, Montana, US)	> 99.9 per cent (captured by persons other than collector)
<i>Piper methysticum</i> (Kava) Ceremonial beverage	Pacific	\$253 - \$2,486	Local Market Price: \$5.95 - \$6.62 (roots, Apia)	97.5 per cent - 99.75 per cent
<i>Prunus africana</i> (Pygeum) Urinary tract disorders	Sub-Saharan Africa, Cameroon	\$991	Collector Price: \$0.17-0.35 for bark.22 (\$35-72 per kg of extract, Cameroon)	94 per cent - 96.5 per cent
<i>Syzygium jambolanum</i> (Jambul), Diabetes	South Asia, Southeast Asia, China	\$641	Farm Price: \$0.125-0.25 (fruit, Philippines) Market Price: \$0.35-0.50 (Los Baños)	> 99.5 per cent (farmer: = 0.05 per cent)
<i>Tabebuia impetiginosa</i> (Pau d'Arco) Digestive	Central/ South America, esp. Paraguay and Brazil	\$1108	Market Price: \$20 (bark, Asunción - US \$0...20 per 10g)	> 95 per cent
<i>Uncaria tomentosa</i> (Uña de Gato, Cat's Claw) Various indications	South America, esp. Peru	\$1164	Collector Price: \$0.24-0.35 (plant material, Peru rainforest) Peruvian Retail Price: \$14.87 - 20.30 (Lima - 20mg bag x 50)	

* per kilogram of active ingredient of sample product for sale in Seattle, July 1999, US\$

** per kilogram of plant material, US \$

Source: From GAIA /GRAIN: Biodiversity for Sale: Dismantling the Hype about Benefit Sharing, *Global Trade and Biodiversity in Conflict*, No.4, April 2000, p. 14

exactly the same as they treat those of their most favoured trading partner.

- Transition periods.
Developed countries were to implement TRIPS within one year after the Agreement was adopted; developing countries had a 5-year transition period—until 1 January 2000; lastly, the transition period of least developed countries (LDC) was established as 10 years—until 1 January 2005.
- Dispute settlement and retaliation.
Countries failing to fulfill TRIPS requirements may be challenged before a WTO dispute settlement mechanism and eventually be subject to retaliatory measures in any segment of their trade.
- Patenting obligations.
Under TRIPS Article 27 (see Box 3), countries are obliged to grant patents for any product or technology, in all fields of technologies. The only exceptions are:
 - ▷ inventions whose utilization is against *ordre public* and morality.
 - ▷ diagnostic, therapeutic and surgical methods.
 - ▷ plants and animals other than microorganisms, although States must grant protection over plant varieties through an effective *sui generis* system.

The inclusion of IPRs in the Uruguay Round negotiations was the direct result of industry pressure over developed countries' governments through their key trade organizations: the International Property Committee (IPC) of the US, the Japanese Federation of Economic Organizations, and the Union of Industrial Employees Confederations of Europe [41]. Industry claimed that the absence of strong IPRs in developing countries was a barrier to trade, costing some US\$200 bn per annum in lost royalties [42]. In fact, the industrialized world holds 97 per cent of all patents, most of which are in the hands of large corporations, and residents of industrial countries hold over 80 per cent of patents granted in developing countries [43].

Furthermore, TRIPS was expressly designed to ensure that IPRs could be universally applied to all technologies, especially those that had previously been declared unsuitable for monopoly rights at the national level—which include pharmaceutical products, food and living beings [42] (see Box 1). For comparison, Spain has granted patents on pharmaceutical molecules only since 1992.

The exceptions to patentability specified in Article 27 are those existing in the European Patent Convention (EPC), to which most EU Member States and other European countries were parties to when TRIPS was negotiated. Developing countries took advantage of the EU's unwillingness to accept patents over plant varieties and animals.

Box 3

TRIPS Article 27: Patentable Subject Matter

1. Subject to the provisions of Paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to Paragraph 4 of Article 65, Paragraph 8 of Article 70 and Paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

The exclusion of plants, animals and essentially biological processes was to be reviewed four years after the entry into force of TRIPS—one year before developing countries' deadline to implement TRIPS, and six before least developed countries' deadline. Launched in 1999, this review is still open.

Article 27.3(b), and the possibility to review it, elicited intense debate about WTO members' obligation to "provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof." The position of developed countries was to strengthen the privileges for industry. For the EU, Japan and the US, this provision indicated the need for all countries to adopt Plant Breeders' Rights (PBR), a special form of IPR covering plant varieties, according to the standards of the International Union for the Protection of Plant Varieties (UPOV). The UPOV system is based in uniformity, distinctiveness and stability and is designed for industrial agriculture. It was clear that the US intended to either include UPOV as the tool to protect plant varieties, or get rid of Article 27.3(b) and its restrictions

to the patenting of life forms altogether. The EU arrived at this review with its homework done. It had approved its most contested piece of legislation, the Directive of the Parliament and the Council on the Legal Protection of Biotechnological Inventions (the European Patent Directive, or EPD), which made the patenting of animals, plants and their parts and genes (including human parts and genes) possible. Therefore, the EU was ready to follow the US.

In contrast, NGOs concerned with small farmers and food security and developing countries took a very different approach to the review, which was articulated in many different positions. Some of them considered that the *sui generis* provision allowed for the development of systems effective to protect farmers' rights to save and develop seed. Yet, for others any *sui generis* system under TRIPS involves the allocation of property rights over plant biodiversity and, therefore, its privatization. All of them asked for an in-depth revision of TRIPS Article 27.3(b), either to ensure the respect of farmers' rights, or to forbid patents on life. In this context, many groups and governments pointed to the achievements that developing countries had obtained under the CBD. These groups started to point to the contradictions between TRIPS and the CBD in order to influence the outcome of the revision of TRIPS Article 27.3(b) in 1999 and the revision of the whole TRIPS in 2000. Perhaps the most known of such analysis was that provided by GAIA/GRAIN in 1998, which is summarized in Table 5.

When 1999 arrived, the review of TRIPS Article 27.3(b) was very high up on the agenda. Countries entered the process with many different proposals. Some official positions (like those of Jamaica, Sri Lanka, Tanzania, Uganda, Zambia and the LDCgroup) proposed that TRIPS should incorporate a provision stating that patents must not be granted without prior informed consent of the country of origin, as required under the CBD; others (like Kenya and Venezuela) asked for the introduction of protection of indigenous knowledge and farmers' rights; others (the LDC) asked for the exceptions of patentability to be extended to all naturally occurring plants and animals, and their parts or to microbiological processes (as proposed by SADC). The African group held the strongest position by asking that the review should clarify that plants, animals, micro-organisms, their parts and natural processes cannot be patented—which would make patents on life illegal under international legislation [44].

The proposals from developing countries could not be more unacceptable to developed countries. Developing countries were firm, though, and, in fact, they were so firm on WTO issues that they forced the failure of the 1999 Seattle WTO Millennium Ministerial Meeting, which finished without any agreement on Article 27.3(b). Consequently, only 30 per cent of WTO developing-country members implemented TRIPS

Article 27.3(b) by the time their deadline materialized on 1 January 2000 [44]. Under the shock of Seattle, WTO did not push strongly for the review of Article 27.3(b)—neither for the whole review of TRIPS, due for 2000. TRIPS focused international attention again when pharmaceutical giants pressed the US government to restrain South Africa from importing royalty-free anti-AIDS medicines from India and Brazil, which do not grant patents on pharmaceuticals. Access to cheap patented medicines was the highest TRIPS-related issue at the Doha WTO Ministerial Meeting of November 2001. The Doha Meeting decided to continue with the discussions on Article 27.3(b) [45].

6.4. Beyond TRIPS, or TRIPS-plus

While international and national NGOs and governmental organizations focused their attention on the discussions around the CBD and TRIPS/WTO, the US, EU and Japan were busy establishing bilateral, regional and subregional trade, investment, aid, science and technology agreements that contain provisions on IPRs that are beyond TRIPS' requirements (named as TRIPS-plus) [46]. After all, TRIPS is about the minimum standards that countries have to implement to avoid non-tariff barriers to trade. TRIPS-plus agreements include the Cotonou Agreement between the EU and African, Caribbean and Pacific (ACP) countries, which forces ACP countries to grant patents to biotechnology inventions, and the currently negotiated Free Trade Area of the Americas, where the US wants no exclusions for plants and animals from patent law. GRAIN and the South Asia Network for Food, Ecology and Culture (SANFEC) denounce these agreements for undermining democracy as they involve only key ministers; push countries to adopt political decisions that should be taken by parliaments; include pre-negotiated dispute settlement processes even less transparent than those of the WTO; and allow developed countries to impose draconian conditions out of sight of their public opinion [46].

7. The Implications of UNCLOS, TRIPS and CBD for Coastal Developing Countries

UNCLOS and the CBD entered into force in the first half of the 1990s. In contrast, as seen above, by June 2001 only 30 per cent of developing countries had implemented provisions of TRIPS as they affect biodiversity. So, while the first impacts of UNCLOS and the CBD have already been felt, those arising from the effective addition of TRIPS are subject to (informed) speculation. Furthermore, neither TRIPS nor the CBD are written in stone: the review of Article 27.3(b) is ongoing and

Table 6
The conflict between TRIPS and the CBD

CBD says:	TRIPS says:	The conflict:
Nation-States have sovereign public rights over their biological resources.	Biological resources should be subject to private intellectual property rights. Compulsory licensing, in the national interest, should be restricted.	National sovereignty implies that countries have the right to prohibit IPRs on life forms (biological resources). TRIPS overlooks this right by requiring the provision of IPRs on micro-organisms, non-biological and microbiological process, as well as patents and/or sui generis protection on plant varieties.
The use or exploitation of biological resources must give rise to equitably shared benefits.	Patents must be provided for all fields of technology, therefore, the use or exploitation of biological resources must be protected by IPR. There is no mechanism for sharing benefits between a patent holder in one country and the donor of material in another country from which the invention is derived.	CBD gives developing countries a legal basis to demand a share of benefits. TRIPS negates that legal authority.
The use or exploitation of traditional knowledge, innovations and practices relevant to the use of biodiversity must give rise to equitably shared benefits.	Patents must be provided for all fields of technology, therefore the use or exploitation of biological resources must be protected by IPR. There is no mechanism for sharing benefits between a patent holder in one country and the donor of material in another country from which the invention is derived.	CBD gives developing countries a legal basis to demand a share of benefits. TRIPS negates that legal authority.
Access to biological resources requires the prior informed consent of the country of origin. It also requires the 'approval and involvement' of local communities.	There is no provision requiring prior informed consent for access to biological resources which may subsequently be protected by IPR.	CBD now gives states legal authority to diminish the incidence of biopiracy by requiring prior informed consent. TRIPS ignores this authority and thus promotes biopiracy.
States should promote the conservation and sustainable use of biodiversity as a common concern of humankind taking into account all rights over biological resources.	The safeguarding of public health and nutrition, and the public interest in general, shall be subject to the private interest of IPR holders as reflected in the provisions of the TRIPS Agreement.	CBD places the public interest and common good over private property and vested interests. TRIPS does the exact opposite.

Source: From GAIA / GRAIN (1998): TRIPS versus CBD: Conflicts between the WTO regime of intellectual property rights and sustainable biodiversity management, *Global Trade and Biodiversity in Conflict* No. 1, April 1998.

the CBD is being developed through voluntary guidelines and protocols. Therefore, States still have some manoeuvring space to build national legislations that best suit their peoples' interests regarding biodiversity.

7.1. Countries' actions to regulate access and benefit sharing (ABS)

Since the CBD entered into force, many countries and international organizations have established several measures to ensure their participation in the benefits arising from the exploitation of their genetic resources. These mechanisms have included the setting of governmental (or regional) policies and legislations, the drawing of contracts between users and providers, and codes of practice and voluntary commitments¹⁴. Countries and supranational organizations that have developed legislations on ABS include the Andean Community, the ASEAN community (inspired by the Philippines), the Organization for African Unity (OAU), India and Brazil¹⁵.

Current regimes on ABS share similar elements, although each regime is unique. One such element is the need for a Prior Informed Consent (PIC). The access-seeking party must inform in advance the provider of genetic resources about the objectives, the economic and the environmental implications of his or her intended actions. Such information must be made understandable to indigenous or local communities involved, if any. The CBD Draft Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization encourage countries to inform, consult and take into account the opinion of indigenous and local communities in their decisions on granting access. Whether this opinion is binding depends on national legislations.

Once the PIC is obtained, access is provided on mutually agreed terms establishing the conditions under which this access is granted and the conditions for the sharing of the benefits. Established benefit-sharing practices vary from country to country, and from contract to contract, but they often include monetary and non-monetary measures. Monetary measures include initial payments, labour, milestones and, if the accessed genetic resources and associate knowledge reach commercialization, a share on the royalties.

Non-monetary measures involve range from the setting up of laboratory facilities to the training of national scientists in the country

¹⁴For a short and clear analysis of existing tools to regulating ABS, consult Seiler A. and Dutfield G. (2002): Regulating Access and Benefit Sharing, *Biotechnology and Development Monitor* 49: 3-7, March 2002. Available at <http://www.biotech-monitor.nl/4902.htm>.

¹⁵For a compilation of these access legislations, visit <http://www.grain.org/brl/abs-brl-en.cfm>.

where the research will be conducted. It is here that States can negotiate their preferential conditions of access to the technology incorporating the genetic resources they provide. UNCLOS provisions on the rights of coastal countries over scientific research in its EEZ (see above) are, in fact, stronger than those of the CBD. Some countries distinguish between academic and commercial objectives with regard to mutually agreed terms for access. However, as illustrated by research on antitumour marine agents, the distinction between public and private research can be highly questionable.

As a result of the CBD, Material Transfer Agreements (MTAs) have become a routine in the exchange of genetic resources. MTAs are contracts that specify the conditions under which access to, and authorized use of, a biological sample is provided, including the conditions under which IPRs can—or cannot—be obtained for them. For example, the exchange of carp and tilapia germplasm within the International Network on Genetics in Aquaculture (INGA) is conducted under MTAs [37].

Countries are not obliged to provide access to their genetic resources. Australia, for example, has closed its hugely wealthy waters to foreign researchers [17]. Therefore, companies interested in accessing and developing active agents from the organisms of Australia's Great Reef Barrier (and from the rest of the countries' coral reef systems) need to do so through contact with national institutions like the Australian Institute of Marine Sciences (AIMS).

7.2. The impact of the CBD on bioprospectors and in patent offices

Four of the main marine bioprospecting teams and experts on the development of marine antitumour agents identified in the course of this research were contacted and their views on the impact of the entry into force of the CBD were elicited. In general, bioprospectors feel—some of them bitterly—that access to marine biodiversity, especially marine invertebrates, is increasingly difficult. John Faulkner even wonders whether the important increase in the number of papers reporting studies on marine microorganisms is due to these access restrictions. An interviewed expert even mentioned one case of corruption at the highest government level as a barrier to access. The CBD is not the only driving force behind bioprospectors' ABS deals with developing countries in order to access their marine biodiversity. The US National Cancer Institute (NCI), the main public funder of the research on antitumour agents, had a policy on the rights of the countries of origin, which was prior to the entry into force of the CBD—which the US has not signed. Indeed, in the absence of evidence of ABS documentation, no active agent

Box 4

Access and Benefit Sharing: Pescanova and PharmaMar

PharmaMar is an ambitious Spanish bioprospecting company, with offices in Madrid and Boston. It is about to launch an anti-cancer compound, ET-743, in the market. It also has many other promising antitumour agents at several stages of the R& D pipeline. PharmaMar expects to earn US\$1 bn from the sales of ET-743 alone.

PharmaMar was founded by José Fernandez Souza-Faro, chairman of Zeltia (PharmaMar's parent company) in 1986 [18]. Zeltia had been funded by José Fernández Lopez, a businessman from Galicia, Spain, who also funded Pescanova, which today owns the world's largest private fishing fleet. Pescanova and Zeltia subscribed to an agreement under which each Pescanova vessel has an expert biochemist on board. This biochemist reviews and collects the organisms that, entangled in fishing nets, get to vessels. By July 2000, this system had been in place for about 10 years and had resulted in an investment of more than US\$53 mn [47].

However, when interviewed, PharmaMar staff are reluctant to talk about the Pescanova-PharmaMar connection. Furthermore, they insisted that, while having scientists on board fishing vessels could be useful, the company is focusing on conducting targeted scuba-diving collection in partnership with national organizations the world over—including Africa, Asia and the US. PharmaMar uses its partner organizations' vessels to perform these collections, and tends to avoid inhabited areas in order to avoid pollution—and perhaps also ABS complications. PharmaMar staff claim that the company is closely monitoring the CBD, and, in particular, the Bonn Draft Guidelines, and that it intends to publicly launch a statement on its corporate ABS policy soon. But then, why is its staff so reluctant to clarify the company's relation with Pescanova?

is allowed to proceed down the regulatory pathway¹⁶.

According to PharmaMar scientific staff, even patent offices are asking for evidence of access and benefit-sharing agreements in order to give course to any patent application involving genetic resources—as has been called for by developing countries' governments within the review of TRIPS Article 27.3(b) and also by working groups at the CBD. The main reason for this move at patent offices, though, is to avoid the uncertainty stemming from the fact that some genetic resources are found in more than one country.

¹⁶Personal communication from the Head of Biodiversity, PharmaMar, June 2002.

7.3. Reality check on fairness and equity

The CBD compromise on access in exchange for the fair and equitable sharing of the benefits (ABS) has created an entirely new market where biodiversity-rich developing countries compete to attract the interest, money and technology of developed countries' corporations. This market is fuelled by "a relatively small number of highly motivated persons who have made benefit-sharing and access to genetic resources their primary professional vocation"—biotrade brokers.

Since the CBD was negotiated, an enormous amount of literature has been written on the subject. Nevertheless, when GAIA and GRAIN investigated the real benefits accrued to local communities, they found out that, to date, there is very little to show in new and substantial benefits being accrued by the South, in general, or by local communities and indigenous peoples, in particular [17].

There is, in fact, very little information on what countries (and indigenous and local communities) are getting from ABS agreements, since this is sensitive commercial information: biotrade brokers often disclose only selected aspects of ABS agreements, out of context. This secrecy fuels competition among biodiversity-rich countries, mainly when they share some or many species—unless such countries decide to promote a co-operative approach to ABS negotiations. Furthermore, whether promised payments deriving from royalties actually materialize depends on whether the (patented) technology successfully reaches the market. However, there are some indicators that "fair and equitable" are often not among the main concerns in ABS deal negotiations.

Good examples of this are the ABS agreements negotiated by Diversa, a US company specialized in accessing, patenting and developing bacterial enzymes. Diversa's agreement with Mexico's National Autonomous University (UNAM) allows it to access the country's microbial biodiversity in exchange of equipment valued at US\$5,000, technical training related to the collection and categorization of samples, US\$50 per sample collected, and royalties on net sales of products developed from materials collected. The level of royalties will vary from 0.5 per cent in the case of pharmaceuticals to 0.3 per cent in the case of other products.

It turned out that Diversa's agreement with the Yellowstone National Park to access the park's extremophile bacteria, challenged in court by a US NGOs' coalition, included 10 per cent royalty transfer: the US got twenty times more than Mexico [48].

There is no indication that marine bioprospecting agreements are fairer and more equitable than their terrestrial equivalents; indeed, there are some indications that they are not. Australia is a case in point. As mentioned above, Australia has closed its waters to foreign scientists. A developed country, Australia is building its own marine biotechnology

capacity. For example, AIMS has established the Marine Bioproducts group, which aims to discover new marine molecules of commercial use in many areas. AIMS itself co-owns a patent with ICI Australia on a sunscreen produced from reef organisms (US Patent 5,637,718). AIMS has signed a biotechnology benefit-sharing agreement with the State of Queensland. The agreement does not deal with AIMS' access to Australian biodiversity, which can only be prevented on environmental grounds. However, it provides the certainty required to secure industrial partners for AIMS' R&D—which need not be of Australian origin.

According to AIMS, non-monetary benefits covered by the agreement include documentation of biodiversity to aid better management, capacity building in this kind of R&D, opportunity for intellectual property development in new discoveries, and the development of a new, innovative, sustainable resource-based biotechnology industry. Monetary benefits include the transfer of 1.5 per cent of net profit received by AIMS as a result of R&D on biological samples obtained from Queensland—not of the net profits the samples generate. This is very ambiguous, and it can vary enormously, depending on the terms under which AIMS licenses its technologies. Altogether, wealthy and developed Queensland has lost control over its marine biodiversity, which AIMS gets to scan for a pittance¹⁷.

Perhaps an unexpected effect of the entry into force of the CBD is the introduction of a new ethos in the conservation policies of developed countries. The conservation of protected areas had traditionally been undertaken by the public sector and financed by public money. Suddenly, protected areas have gained commercial value, which is often perceived by the managers of those areas as a source of complementary income to finance their own scientific activities. Accordingly, they proceed to sign ABS agreements with the private sector that alienate the rights of the public over them. The slope between selling access to conserve and conserving to sell access might be a slippery one, though.

7.4. TRIPS, CBD and State control over biodiversity

It may be argued that the ABS scene will improve with time, as countries gain more experience, ABS guidelines are implemented, and the technologies covered by ABS agreements start to deliver royalties. In contrast, the pressure on developing countries to grant patents over their genetic resources is forceful and immediate.

The CBD obliges each member State to acknowledge and respect IPRs on the technologies and inventions derived from its genetic resources

¹⁷The presentation of the Biotechnology Benefit Sharing Agreement between AIMS and the State of Queensland is available at <http://www.aims.gov.au/pages/about/corporate/bsa-aims-qld.gov.html>.

if these are obtained through a prior informed consent and terms for the sharing of resulting benefits are mutually agreed—even if the deal is reached by another member State. Consequently, this would force countries to acknowledge IPRs on the technologies and inventions based on genetic resources under their sovereignty—no exceptions are mentioned.

Under TRIPS, countries are also obliged to accept IPRs over all products and technologies, including microorganisms. Until Article 27.3(b) is reviewed, countries may exclude plants and animals from patenting, but there are strong pressures to lift these exceptions. The ever-widening scope of international patenting practices and TRIPS-plus bilateral, subregional and regional agreements also add to the pressure on developing countries to progressively accept private ownership over their genetic resources, regardless of whether they granted access to them or not. At that moment, countries will be left with very little options to conserve and sustainably develop biodiversity, and so will their indigenous and local communities.

Developing countries must react strongly to avoid such appropriation of the biodiversity—at least in their territories. Action may include:

1. Taking advantage of the manoeuvring space left by the interpretation of TRIPS: This would include establishing IPR regimes that, *inter alia*, define 'discovery' in a way that prevents the patenting of any substance already existing in nature; exclude plants and animals of patentability; include stringent novelty requirements that include prior oral disclosure anywhere in the world; and do not allow for broad claims over inventions [49]. However, these measures can be short-lived as pressure to adopt developed countries' standards increase.
2. Establishing rights regimes ensuring the inalienability of indigenous peoples' and local communities' rights to access, conserve and sustainably develop biodiversity: Such rights should be a priori and the rights of other users of genetic resources would be subordinated to them—exactly the opposite of what is happening within CBD negotiations. There are conflicting opinions on whether the rights of indigenous peoples and local communities should be established under the WTO, which deals with trade. WTO has the advantage that, through cross-retaliation, sanctions are enforceable; in contrast, the undemocratic dispute settlement and arbitration mechanisms at WTO are a disadvantage, as they could establish that measures to protect indigenous peoples and local communities are barriers to trade. A further problem with TRIPS is that it deals with property rights, and property is alienable and can be bought and sold. Therefore, the rights of indigenous peoples and local communities should be established outside TRIPS and must be above and beyond WTO

jurisdiction, just as human rights are—nobody can point to the enforcement of human rights as a trade barrier.

3. Joining the African Group position that the review of TRIPS Article 27.3(b) should clarify that plants, animals, micro-organisms, their parts and natural processes cannot be patented: Developing countries may be worried by the fact that a ban on patents on plants, animals, micro-organisms, their parts and natural processes would automatically threaten their expectations under ABS agreements. However, forbidding patents on life does not mean that incentives for the scientific development of genetic resources are not urgently needed. In fact, many scientists wonder whether the explosion of patents in biotechnology fosters innovation or, instead, stifles it. The patent system is showing its limitations in the case of marine antitumour development—where the time required for R&D is much more than that provided by patent protection [22].

8. The Implications of TRIPS and the CBD for Coastal Communities

8.1. TRIPS, coastal indigenous peoples and local communities

TRIPS has no explicit say about indigenous peoples or local communities, coastal or otherwise. Implicitly, it ignores them and hence it facilitates the appropriation of their biodiversity and associated knowledge. For example, US law, unlike the law in force in most other countries, does not consider that ‘novelty’ is lost when an invention has been divulged outside the US by non-written means, such as public use and sale [49].

Once developing and less developed countries have established their IPR systems, US corporations are likely to put pressure on these countries to accept the patents they have been granted at home. In fact, some TRIPS-plus agreements already entail the acknowledgement of US patents in *partner* countries.

Furthermore, there is a trend towards the development of supranational patent offices—currently it is national governments who grant or refuse IPRs. The EU is designing a European Patent that would be enforced in all its member States. Nobody knows where this trend will lead to, but the integration of patent authorities is more likely to suit the interests of transnational corporations than those of much less powerful indigenous and local communities.

The high visibility of the debate on the ownership of biodiversity and the highly publicized conflict between the CBD and TRIPS has forced the IPR establishment to take indigenous and local communities knowledge systems into account. Its main effort to do so has been WIPO’s

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

The Intergovernmental Committee has discussed intellectual property issues in the context of access to genetic resources and benefit-sharing; protection of traditional knowledge, whether or not associated with those resources; and the protection of expressions of folklore [50]. WIPO's effort aims to include TEKS into (the logics of) IPR regimes. Such 'soft' IPR systems would then be incorporated into TRIPS, and, hopefully, put an end to the debate on the contradictions between TRIPS and the CBD. The real danger of this is that in these discussions TEKS are defined in the light of IPRs, rather than in the light of their own histories and needs.

Furthermore, this move transposes the assumptions underlying industrial IPR regimes—the common good is favoured by the monopoly of knowledge, and that such monopoly can be bought and sold—to societies relying on the options arising from the direct use of biodiversity, where knowledge is spread and exchange, vital for survival.

8.2. The CBD, indigenous peoples and coastal communities

The CBD establishes that the definition and protection of the rights of indigenous and local communities are subject to national legislation. As seen above, current work within the CBD (a) stresses indigenous and local communities' participation in ABS negotiations, rather than their own contribution to biodiversity conservation; and (b) grants WIPO authority in defining the rights of indigenous and local communities, instead of defining them aside of IPRs.

The definition of indigenous and local communities' rights in the IPR blueprint may hide a trap: limiting such rights to those groups' knowledge of particular uses of particular species. Furthermore, it reduces knowledge of biodiversity to knowledge of single species.

What should be protected, though, are the rights of indigenous and local communities to exert control on the biodiversity they depend on—which, in one form or another, is a result of biocultural diversity and associated TEKS. This is especially relevant for the indigenous and coastal communities who do not exploit the invertebrates targeted by bioprospectors but who rely on the ecosystems that hold such species.

It is also relevant for First Nations in whose territories spawn the wild species of salmon necessary for the aquaculture industry. The contribution of indigenous peoples' and coastal communities' traditional management systems to biodiversity conservation is increasingly acknowledged. Therefore, rights of coastal and riverside indigenous and local communities to continue conserving biodiversity should be protected under the CBD.

Such rights should be a priori rights, collective and unalienable. Their enforcement should ensure communities' control over the biodiversity they rely on and should promote their further development. Much thinking has gone into how such rights systems would look and how they would be integrated into the international regulatory framework defining control over biodiversity. Biocultural diversity does not facilitate the task, but makes it more challenging.

9. Conclusions and Recommendations

9.1. A resumé of findings and conclusions

From the facts above, it can be concluded that:

- Coastal communities have been largely marginalized in the international debates on the control over biodiversity.
- Scientific knowledge of marine biodiversity is incomplete and scattered. This ignorance applies both to our capacity to develop the 20,000 marine substances, and to assess and forecast the impact of human activities.
- Today's coastal marine biodiversity is largely a result of the traditional management systems, an expression coastal indigenous peoples and local communities' traditional ecological knowledge systems (TEKS).
- Coastal communities' TEKS also include the use of marine biodiversity to suit many needs other than food, including medicinal use. Such uses, though, remain largely unpublicized and poorly understood.
- The pharmaceutical industry seems to be less reliant on indigenous and local communities' knowledge of the medicinal use of marine biodiversity than on local use of medicinal plants.
- The prospects for local communities' ability to benefit from sustainable fisheries on marine molecule producing organisms are shaped by industry's use of professional scuba divers and its progressive shift towards marine micro-organisms and genetic engineering as a means to find and obtain new molecules.
- The aquacultural industry is proceeding to domesticate cultivated species. However, the wild fish populations that hold the genetic resources necessary for this domestication are being eroded by many causes, including aquacultural operations themselves. This contradiction has led to an increase in the *ex situ* conservation of fish germplasm and to the increasing application of IPRs over fish genetic diversity.

- The CBD establishes three sets of rights:
 - ▷ the sovereign rights of States over biodiversity;
 - ▷ the rights of the holders of industrial technology, who enjoy IPRs and may keep their information confidential; and
 - ▷ the rights of the holders of TEKS, which are subject to national legislation, and whose knowledge must be made publicly available.
- Both TRIPS and the CBD are evolving processes. The review of Article 27.3(b) is still open, as are the CBD provisions, including those relative to the rights of indigenous and local communities.
- Current work within the CBD (a) stresses indigenous and local communities' participation in ABS negotiations, rather than their own contribution to biodiversity conservation; and (b) grants WIPO authority in defining the rights of indigenous and local communities, instead of defining them aside of IPRs.
- According to industry sources, one of the demands of those working for the rights of indigenous and local communities in developing countries, that the granting of patents be subject to evidence of PIC of the country of origin, is now a practice in some patent offices. This is a defensive move aiming to prevent patent challenges by countries holding the genetic resources or associated knowledge contained in the patents.
- The pressures for developing and least developed countries to allow the patenting of genetic resources and living beings are so strong, both under TRIPS and under TRIPS-plus agreements, that countries could find, in the mid-term, that the sovereignty of their biodiversity has been appropriated through IPRs.
- To avoid this, countries need to establish rights regimes ensuring the inalienability of indigenous peoples' and local communities' rights to access, conserve and sustainably develop biodiversity. Such rights should be a priori rights, collective and unalienable, and the rights of other users of genetic resources and biodiversity would be subordinated to them.
- The CBD offers a space for countries to provide such rights—provided that they are established independently from the frame of IPRs, as is now happening.
- The rights of indigenous and coastal communities who have maintained and preserved marine biodiversity through their traditional management systems should be protected under the CBD.

9.2. A role for ICSF?

This report is a first attempt to look at issues in marine biodiversity from a perspective that is new for the International Collective in Support of Fishworkers (ICSF)—that of the use of marine biodiversity for purposes other than food; or, in other words, that of the control over coastal communities' intellectual knowledge of marine biodiversity.

- A first conclusion is that the issue of the rights over resources deriving from knowledge is not such a new issue to ICSF, which, as an organization, has been fighting, for many years now, for the rights of coastal communities to their traditional fishing grounds. ICSF has been decisive in the increasing recognition of the contribution of coastal communities' traditional management systems to the marine biodiversity we all enjoy.
- One of the main purposes of this research exercise was to look at the richness of coastal communities' TEKS on marine biodiversity. The main finding is that these systems remain largely unpublicized and poorly understood. In the face of the current hype on knowledge misappropriation—either mediated by ABS agreements or not—ICSF should ensure that any effort to fill this gap goes beyond mere documenting to providing active support to the further development of TEKS, towards better management of coastal and marine resources and towards strengthening traditional medicinal systems.
- ICSF can build its political analysis and its capacity-building activities around the issues concerning the knowledge and maintenance of biodiversity, at species and ecosystem levels, for food or for any other use—in a way that enriches, rather than modifies, its current programmes.
- ICSF has much to gain from monitoring the CBD and TRIPS and joining organizations working to promote community rights over biodiversity. In this work, ICSF should make sure it is linked to real stakeholders and/or their representatives. It should also always critically assess whether its actions—and those of its partners—promote the privatization of biodiversity, albeit in an indirect way.

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