

## **Note on Emerging uses of Living Marine Resources Drugs from the Sea: Issues of Biodiversity and Livelihoods<sup>1</sup>**

Local and indigenous coastal communities in India, as elsewhere, have interacted closely with the coastal ecosystem for generations. They have intimate knowledge about fish and other available resources in the ecosystem. In other words traditional ecological knowledge (TEK) systems are highly evolved within these communities. Coastal and marine resources such as fish, coral and seaweed have been used for various purposes, including as food, housing, health supplements and as medicine. For example, a search of the Honey Bee database on grassroot innovations<sup>2</sup> shows the many uses of fish and fish products as medicine, pesticide and fertilizer. Through judicious use of coastal and marine resources over generations, coastal communities have played vital roles in conserving and managing coastal marine biodiversity. They have shaped, and have been shaped by, the ecosystem that they have inhabited. Their livelihood continues to depend on coastal biodiversity and access to it.

For the past few decades, however, the intensifying pressures on coastal resources have had several implications for coastal communities, including those who have been fishing for their livelihood. The pressure on fish resources, a result of technological changes as well as market forces, has reached unsustainable levels. The pressure on coastal lands and resources, primarily due to industrialization, urbanization and tourism, has increased considerably. Habitat degradation, especially due to pollution, is increasing by the day. These are some of the factors that are threatening the life and livelihood of these communities and the ecosystems on which they depend.

It is imperative to highlight these issues and to find ways to deal with them. However, it is as important to keep in mind other emerging uses of marine resources and spaces, and the potential implications for coastal biodiversity and the populations that relate to, and depend on, this. In recent years as the understanding about the oceanic ecosystem has expanded, the potential uses of oceans, covering 70 per cent of the earth's surface, have expanded considerably. For example, efforts to harness the temperature gradient that exists between the cold water of the depth and the warm water in the surface layer of the tropical seas (Ocean Thermal Energy Conversion (OTEC)) have been underway for a few decades, and are set to increase. With a water crisis building up in several parts of India and elsewhere, and especially in coastal cities and towns, desalination plants using seawater are also likely to increase. At the same time, the potential offered by the seaweed industry is likely to see a growth of mariculture activities along the coast. Multinational corporations are already beginning to invest in this sector, as is happening in Ramanathapuram district, Tamil Nadu. Brackishwater and marine aquaculture is rapidly growing along the Indian coast, and is being projected as an activity vital to meet the food needs of future generations.

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<sup>1</sup> This note is largely based on the draft ICSF Working Policy Paper titled 'The Impact of TRIPS and the CBD on Coastal Communities', by Anna-Rosa Martinez Prat (2002). International Collective in Support of Fishworkers.

<sup>2</sup> [http://202.71.129.184/nifindia/innovation\\_database.asp](http://202.71.129.184/nifindia/innovation_database.asp)

This note will concentrate mainly on the growing use of marine biodiversity for pharmaceutical purposes.

### **Marine bioprospecting and the pharmaceutical industry**

Marine bioprospecting is the collection and testing of marine living organisms for the purpose of developing new products with pharmaceutical, agricultural and/or industrial applications. Potential commercial applications from marine bioprospecting research include commercially valuable anti-cancer agents, nutraceuticals, natural products to fight disease, ultra violet filters, plant growth regulators, antifoulants and environment cleansers.

It is significant that marine species differ much more among each other than their terrestrial equivalents. Only 5 out of the 33 existing animal phylum are not represented in the marine environment, while 13 of them are exclusively marine. This means that genetic, biochemical and physiological animal diversity is much larger in the oceans than on land.<sup>3</sup>

In an article in *The Scientist* titled 'Oceans: Medicine Chests of the Future', Rayl (1999)<sup>4</sup> quotes marine chemist Bill Fenical, director of the Center for Marine Biotechnology and Biomedicine, Scripps Institution of Oceanography in the US:

*There are one million cells in one milliliter of seawater and they're all different, yet we know something about only one or two percent of those. The oceans are a huge resource for drugs and other products in agrichemicals and skin care ..., and we are discovering new things all the time.*

Marine organisms produce chemicals for their own use in a diverse array of functions including defence, offence and signalling. The resulting chemical arsenal evolved for these purposes is the focus of research to discover compounds that may be developed by industrial partners into clinically useful drugs. Coral reefs are known to be prime candidates for potential drugs.

Research organizations, especially in the developed world are working hard to realize the potential offered by the marine ecosystem. Such research has been underway since the 1960s. In India the National Project on Development of Potential Drugs from the Sea was initiated much later, in November 1990 (DOD, 1993)<sup>5</sup>. Research has been continuing since then, coordinated by the Central Drug Research Institute (CDRI), Lucknow. The CDRI publishes a regular newsletter titled 'Ocean Drugs Alert' and arranges periodic workshops and symposia (See box for more information).

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<sup>3</sup> Heip C, "Un océan de diversité", *Biofutur* 179: 12-17

<sup>4</sup> Rayl, AJS: Oceans: Medicine Chests of the Future? *The Scientist* 13[19]:1, Sep. 27, 1999 ([http://www.the-scientist.com/yr1999/sept/rayl\\_p1\\_990927.html](http://www.the-scientist.com/yr1999/sept/rayl_p1_990927.html))

<sup>5</sup> [http://dod.nic.in/vsdod/ayr92-93/ar\\_respr.htm](http://dod.nic.in/vsdod/ayr92-93/ar_respr.htm)

### **Development of Potential Drugs from Ocean:**

India is endowed with a rich marine biota all along its 8,000 km coastline. The coral reefs that occur in her tropical water demonstrate the highest level of known diversity among marine species. The marine diversity is largely unexplored and, therefore, offers a great challenge and opportunity for new discoveries. A national project on 'Drugs from Sea' was taken up by DOD during 1990-91. This project is being implemented by involving ten institutions with the Central Drug Research Institute (CDRI), Lucknow, as the nodal agency for implementation.

Over 800 different species of marine flora and fauna collected from Indian coasts including island groups were subjected to investigations to identify bioactive compounds. During the last few years, about 4,000 samples were extracted/fractionated and subjected to a wide spectrum of screening for biological activities such as antidiabetic, anti-hyperlipidaemic, antidiarrhoeal, antimicrobial/ antiviral, antimalarial, and so on. 597 samples exhibited various types of biological activities and out of these 16 samples were identified for follow-up studies in different areas.

The following organisms mentioned in code numbers have been taken up for product development.

1. CDR Antidiabetic/Antidiarrhoeal
2. CU1/002/004 Antihyperlipidaemic
3. NIO - 450 Antianxiety
4. AU-2-106 Antioxidant/ Antihyperlipidaemic/ Antihyperglycaemic
5. CBM-089 Antibacterial/Antifungal/ Larvicidal
6. 11C - 276 Larvicidal

Over the years, 319 pure compounds have also been isolated. Some of these possessed interesting biological activities while some others, though inactive, had novel chemical structures, like alkaloids, glycosides, aminoacids; fatty alcohol esters and so on. Ocean organisms have been widely used in the *Ayurvedic* system of medicine. The DOD is trying to use these organisms and the results available till date are encouraging.

The report from the 73<sup>rd</sup> Annual General Meeting of the ICAR Society on 16<sup>th</sup> July 2002, notes that 'The sleeper Peptides, a potent analgesic agent, has been isolated from the salivary gland secretions of the marine cone snails.

In general, however, it is countries of the North who have the knowhow, capital, human resources and technology on these aspects, while it is countries of the South who have the genetic resources. For example, patents of all the antitumour drugs of marine origin that have been either commercialized or are at the stage of human clinical trials, are held by companies or institutions in the North, primarily from the US, Japan and Europe. The

North, therefore, asks for stricter Intellectual Property Rights (IPR) regimes that may guarantee the biotech industry the recovery of their investments and costs, plus profits. The South, in contrast, is more concerned about compensation for use of resources and equitable benefit sharing arrangements.

Given the circumstances it is in the interests of Southern countries to be proactive in putting together appropriate policy and regulatory frameworks. Such a framework should be effective in:

- protecting the interests of local communities traditionally using, and knowledgeable about, these resources;
- ensuring a fair deal to States;
- protecting marine biodiversity from damage as a result of bioprospecting and other research activities; and
- preventing biopiracy;

With respect to the issue of biopiracy, there are already several examples where genetic samples of marine organisms have been collected and patented by corporations and institutions from Northern countries, without the knowledge or permission of States, or without satisfactory access and benefit sharing arrangements. In this context the recent initiative by China, Brazil, India, and nine other of the world's most biodiverse countries (formally known as the Group of Allied Mega-Biodiverse Nations) to form an alliance against biopiracy and press for rules protecting their people's rights to genetic resources found on their land, is significant, though not without problems.<sup>6</sup> There are also some lessons to draw from Executive Order 247 (EO 247) of The Philippines establishing the provisions and legal procedures in the utilization of natural resources for scientific studies and commercial purposes.

It needs to be stressed that policies that recognize TEK systems and the need to actively support them would be in the best long-term interests of local communities and countries, and would prevent the appropriation of local knowledge and biodiversity.

### **The international legal framework of control over marine biodiversity**

National legislation and frameworks for use of marine diversity will need to be in accordance with international law. The international community deals with control over marine biodiversity mainly through the following conventions and agreements: The 1994 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 Organisation (WTO). Relevant aspects of these agreements are briefly mentioned.

#### *The United Nations Convention on the Law of the Sea (UNCLOS)*

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<sup>6</sup> Mark Stevenson: 'China, Brazil, India, 9 other nations form alliance against biopiracy' Tuesday, February 19, 2002, Associated Press

This important Convention entered into force in 1994. It is relevant to control on biodiversity as (1) it establishes the rights and obligations of coastal states on the marine areas adjacent to them, and (2) it sets the conditions to conduct marine research.

(1) UNCLOS allows for the establishment of a territorial sea upto 12 nautical miles. UNCLOS also allows the creation of 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"<sup>7</sup>. 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' sovereignty rights into the seas.

(2) 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. In the EEZs, these rights are modulated by the obligation, in normal circumstances, to grant other States and nationals consent for marine scientific research<sup>8</sup>. These States and nationals are also subject to a number of obligations, including informing on the research activities, accepting the coastal state participation in research programmes, and providing access for the coastal state to all data and samples derived from the marine scientific research project<sup>9</sup>. Such provisions oblige any company wishing to carry on bioprospecting activities to inform coastal countries of this. This is a first step towards the concept of "Previous Informed Consent" developed under the CBD.

#### *Convention on Biological Diversity (CBD)*

The CBD acknowledges the sovereign rights of countries over their biodiversity. It conditions access to genetic resources to prior informed consent by countries and the fair and equitable sharing of the benefits arising from the industrial utilization of these resources. Article 1 of the CBD states that:

"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. The CBD establishes that States have **sovereign rights** to exploit their own resources<sup>10</sup>. Simultaneously, the Convention acknowledges **IPRs** on the technologies and products derived from the use of those genetic resources<sup>11</sup>. Therefore, the states that are parties to the CBD must abide by national sovereignty and IPRs. The CBD also acknowledges the

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<sup>7</sup> UNCLOS Art 56

<sup>8</sup> UNCLOS Art. 246

<sup>9</sup> UNCLOS Art 249

<sup>10</sup> CBD Art 3.

<sup>11</sup> CBD Art 16

need to “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”<sup>12</sup>. 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 Convention on Biological Diversity thus acknowledges the vital role of traditional knowledge, innovations and practices in biodiversity conservation and sustainable development as well as the need to guarantee their protection, whether through IPR protection or other means. However, the rights of these “indigenous and local communities” are not explicitly recognised 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 in this regard.

### *TRIPS*

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organisation (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).

Under Article 27 of TRIPS, countries are obliged to grant patents over 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.

It was agreed that Article 27(3)(b) on the patenting of life forms would come up for review four years after the entry into force of the TRIPS Agreement, that is in 1999. Presently, the efforts of developed countries favouring the patenting of life forms have been checked by developing countries. Among the proposals put forward by developing countries are the following: that TRIPS should incorporate a provision that patents must not be granted without prior informed consent of the country of origin, as required under the CBD; that indigenous knowledge and farmers’ rights must be protected; or that the exceptions of patentability should be extended to all natural occurring plants and animals, and their parts or to microbiological processes. The African Group has held the strongest position by asking that the review should clarify that plants, animals, microorganisms, their parts and natural processes cannot be patented, which would make patents on life illegal under international legislation<sup>13</sup>. There is no consensus as yet on these issues despite three years of debate.

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<sup>12</sup> CBD Art. 8(j)

<sup>13</sup> GRAIN (2000) *For a Full Review of TRIPS 27.3.(b): An update on where developing countries stand with the push to patent life at WTO*, p. 6. Available at: <http://www.grain.org/publications/trips-countrypos-en.cfm>

It needs to be noted that there is an ongoing debate about the coherence between TRIPS and the CBD. This debate has, among other things, focused on some of the following aspects: (i) according to the principle of national sovereignty enshrined in the CBD, countries have the right to regulate access of foreigners to biological resources and knowledge, and to determine benefit-sharing arrangements. TRIPS, on the other hand, enables persons or institutions to patent a country's biological resources (or knowledge relating to such resources) in countries outside the country of origin of the resources or knowledge. (ii) Article 15.4 of the CBD states that "access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party." In TRIPS, there is no provision that applicants for patents or other IPRs over biological resources have to obtain prior informed consent. There is thus no recognition in TRIPS of the rights of the country in which the biological resource or knowledge of its use is located. (iii) While a key emphasis in CBD is on benefit sharing arrangements, under TRIPS there is no provision for the patent holder on claims involving biological resources or related knowledge to share benefits with the state or communities in countries of origin.

### **Fishing communities: Areas of concern**

From the perspective of fishing communities these developments need to be carefully monitored in terms of the following aspects:

- a) *Access to fishing grounds and to coastal spaces traditionally inhabited and used by fishing communities* (for sorting and drying fish, for beaching their craft, for repairing nets etc.): Areas rich in biodiversity are also likely to be areas that fishermen have traditionally fished, and there could be a space conflict. As the commercial returns from bioprospecting activities become significant, it is possible that administrative measures to give a fillip to bioprospecting activities are adopted, through, for example the establishment of protected areas, that in effect, block access of fishermen to rich fishing grounds or coastal resources.
- b) *The impact on marine biodiversity and coastal ecosystems*: Bioprospecting and bioharvesting activities may have negative impacts on coastal and marine ecosystems and thereby on fisheries-based livelihoods, and this aspect needs to be carefully monitored. As collecting is an extractive process there is potential for environmental impact. At the bioprospecting stage a relatively small quantity of a large number of organisms is taken for general primary screening purposes. 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 gram per tone) from the sea hare *Dolabella auricularia* from the Indian Ocean. Such large collections were made (1600 kg) that this project has been criticised as an assault on biodiversity conservation<sup>14</sup>. Dolastatin 10 was subsequently synthesised and the molecule could follow its way through the clinical evaluation process.

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<sup>14</sup> Faulkner J, "Marine pharmacology" *Antonie van Leeuwenhoek* 77: 135-145, 2000.

In general, going by the experience so far, the environmental impact of the development of marine drugs differs with the biology of the exploited species and their active agent concentration and complexity. A clear distinction needs to be drawn between the bioprospecting phase and bioharvesting, where large quantities of a targeted organism are collected and wild populations are unlikely to prove an ecologically sustainable source. At this phase, bioprospectors need to collect large amounts of organisms, obtain them through mariculture, or chemically synthesize the active agents.

Industry prefers synthesis because it then can obtain derivatives with improved action or less negative side effects. However, most marine active agents are highly complex and prove very difficult and expensive to synthesize. Some companies, therefore, continue to rely on wild populations to feed their studies while others invest in cultivating marine invertebrates as a way to ensure and increase their supply.

It is worth noting that 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 would need to 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 if the quantities required are not possible through mariculture.

For example, PharmaMar, which has patented EY-743, a marine anti-tumour agent from the sea skirt, *Ecteinascidia turbinata*, to meet its estimated market of 2.5 kilos of ET-743 a year, would need to grow as much as 2 500 tonnes of *E. turbinata* through mariculture operations, apart from actual collection. Therefore, in parallel to its mariculture projects, the Spanish firm has developed a synthesis process for ET-743.

- c) *The appropriation of local knowledge*: Bioprospecting activities may make use of the traditional knowledge base of coastal fishing communities, either in locating biodiversity or in identifying species and their useful features that have traditionally been used by them for medicinal or other purposes. The earlier quoted INSA publication, for example, mentions that 'Ocean organisms have been widely used in the *Ayurvedic* system of medicine'. In this context it is worth monitoring if such activities take place with the knowledge of local communities and with measures in place to protect local interests.

## **Agenda for Action**

### ***(1) Sustainable use and management of marine resources***

It is evident that the oceans still keep many secrets and continue to yield new surprises. It is a humbling fact that we still know very little about the marine ecosystem, the interactions between its components, and the biodiversity it holds. We know little of the value of marine genetic resources, their inter-relationships and their potential commercial importance. There can be no stronger case for adopting a *socially-just ecosystem approach* to management of coastal and marine resources. The quest must be to protect

and manage the coastal and marine biodiversity using an ecosystem approach (the elements of which will need to be worked out), in ways that also sustain local livelihoods. By the same logic there is a strong case for adopting a *precautionary approach* to oceans use, in keeping with Principle 15 of the Rio Declaration that States shall not use lack of full scientific certainty as a reason for postponing cost-effective measures to prevent environmental degradation, where there are threats of serious irreversible damage.

## ***(2) Sustaining livelihoods of fishing communities***

In keeping with spirit of Agenda 21, the effort must be to manage resources while sustaining the livelihoods of those dependent on natural resources such as fisheries. Focusing specifically on the emerging uses of marine resources and space, the following actions would be relevant:

- a) There is little available information about the traditional knowledge of coastal communities, including fishing communities about marine and coastal resources. It would be important to document this in ways that protect the interests of these communities, rather than make available their knowledge to prospectors. It is also in the interests of States to grant *a priori* and inalienable rights over these TEK systems, as this would prevent their misappropriation through IPRs.
- b) As provided under CBD Article 10 (c), it is important to go beyond mere documenting to providing active support to the further development of TEK systems, towards better management of coastal and marine resources and towards strengthening traditional medicinal systems. This will also ensure that such knowledge systems are valorized and not eroded over time.
- c) In coherence with CBD Article 8(j), the State should ensure that the rights of local fishing communities to both land and marine resources traditionally accessed by them, is protected by national legislation. These rights must be accompanied by the obligation to manage resources in a sustainable way.
- d) The State should also ensure that fishing communities are recognized as decisive stakeholders, where bioprospecting activities make use either of resources that they have traditionally enjoyed access to, or of their knowledge of coastal and marine resources. They must be given the right to have a decisive say in the way resources are to be used, subject to sustainable utilization of resources. For example, the Executive Order 247 (EO 247) of The Philippines stresses that: “Prospecting of biological and genetic resources shall be allowed only with the prior informed consent of the concerned local communities”.
- e) It should be obligatory for Indian or foreign agencies engaging in bioprospecting activities in India to make available information on existing/ongoing bioprospecting activities, especially to fisherfolk in locally understandable terminology and language.

There also needs to be some debate on benefit sharing arrangements as this is undoubtedly a complex issue. Legislation adopted by other developing countries that make provisions for such arrangements will need to be studied. In a marine context, perhaps it can be specified that returns arising out of the utilization of

coastal and marine genetic resources, must be utilized to sustain the livelihoods of fishing communities, to support traditional knowledge systems and for sustainable management of marine and fisheries resources.

***(3) Retaining control over biodiversity***

While this remains a contentious issue, it would appear that if countries and communities of the South are to retain control over their biodiversity, they must oppose, or radically limit, the patenting of all life forms during the review of Article 27 (3)(b) of the TRIPS Agreement and in other relevant international fora. Taking advantage of the space left by the interpretation of TRIPS, this could include establishing IPRs regimes that, *inter alia*, define “discovery” in a way that prevents the patenting of any substance already existing in nature; exclude plants and animals from patentability; or include stringent novelty requirements that bring in all the CBD requirements including prior oral and recorded disclosure, consent of concerned communities, and equitable benefit-sharing arrangements with such communities, anywhere in the world.

Bioprospecting is being seen as a tool for Biodiversity Conservation, as an alternative means of livelihoods from the sea, in several countries and by several organizations.  
([http://www.cerc.columbia.edu/training/forum\\_01cs/TuiwawaCS.html](http://www.cerc.columbia.edu/training/forum_01cs/TuiwawaCS.html))