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Original research article

Role of marine bioprospecting contracts in developing access and benefit sharing mechanism for marine traditional knowledge holders in the pharmaceutical industry

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ABSTRACT

The remarkable growth of bio-based industry has led to a rapid increase in the bioprospecting activities. The marine biomes are a rich reservoir of unique life systems making them an attractive target for bioprospecting for identification and development of potential drug molecules for human therapeutics. Many of the drug molecules such as ara-c, trabecetidin and eribulin have been discovered from marine organisms. It is noteworthy that indigenous communities have developed, preserved as well as evolved the marine traditional knowledge from one generation to next. Pharmaceutical companies utilize marine life based traditional knowledge developed by the communities at various stages of drug development, unfortunately, many a times without having a mechanism of access and benefit sharing in place. One such example is the marine bioprospecting Fiji contract that illustrates the role played by Fijian community and the lacuna in access and benefit sharing mechanisms. The present study is an attempt to explore the mechanism of fair and equitable sharing of the benefits arising from use of marine bioresources with the local communities as marine traditional knowledge holders in marine areas. It briefly describes the various international conventions and protocols that emphasize on the development of fair and equitable benefit sharing mechanisms. The study proposes marine bioprospecting contracts that are based on mutually agreed terms among the key stakeholders (the State with the genetic resources, traditional knowledge holders and marine bioprospectors). Marine bioprospecting contracts eventually will need to be customized as per the legislation of a country because of territorial nature of law. Also, the marine bioprospecting contracts will differ from other bioprospecting contracts due to various unique parameters associated with the activity such as economics of deep sea explorations (expensive processes of exploration and sample extraction), continuous supply of sample, the jurisdiction of marine areas and traditional knowledge associated. The present study elucidates the concept of marine bioprospecting contracts by considering India as a case study emphasizing sharing of benefits with traditional knowledge holders as well as ensuring sustainable use of marine genetic resources by the pharmaceutical sector.

Abbreviations: ABS, Access and benefit sharing; CBD, Convention on biological diversity; CAGR, Compound annual growth rate; TRIPS, Trade related aspects of intellectual property rights; UNCLOS, United Nations Convention on the Law of the Seas (UNCLOS); WHO, World Health Organization; WIPO, World Intellectual Property Organisation; WTO, World Trade Organization.

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1. Introduction

Nature has always been a source of inspiration and has played a critical role in drug discovery and development process (Ji et al., 2009). Drug molecules and compounds were identified from plants, animals and microorganisms. Slowly the interest from terrestrial to marine bioresources has shifted as a result of the adventitious properties offered by the marine chemical compounds (Montaser and Luesch, 2011). Marine ecosystems are unique and rich reservoir of biodiversity with an enormous potential towards improving the quality of human life. The modern medicine system endeavours to make use of these marine flora and fauna in several possible ways. Pharmaceutical sector is the major area that is actively building its inventory of marine bioresource based/derived drugs. Some of the determining parameters for increased corporate interest in the marine genetic resources include requirement to combat multi drug resistant, novel drug discovery that is low shelf life of conventional drugs and increasing market demand of bio-based drugs. Marine organisms have highly developed defense system in order to survive in the hostile conditions such as extreme temperatures, varied pressures (low or high), low energy and lack of sunlight.

Thus, marine organisms offer a unique genetic pool that may possess the potential of treating several diseases including rare diseases or the ailments that are still considered incurable (Demunshi and Chugh, 2010; Lazcano-Pérez et al., 2012). This can be effectively deduced from the successfully FDA approved drugs (Table 1) such as Cytarabine (Ara-C), vidarabine (Ara-A), ziconotide, trabectedin, eribulin mesylate (Mayer et al., 2010; Martins et al., 2014). Marine organisms also find use as model organism from the perspective of understanding various fundamental phenomenon of life which have not been yet unravelled. One such example is elucidation of vertebrate development process through zebrafish embryo (Ingham, 1997). Interestingly, the bioprospecting practices using marine bioresources are not new as indigenous communities have been dependent on these resources for food, medicine and livelihood since the inception of human civilization. However, as today's world progresses towards the age of the bio based economy, bioprospecting activities for several reasons including human health care have increased rapidly. Bioprospecting in general has been defined in various ways by different authors and organizations. "TRIPS, CBD and Traditional Medicines: Concepts and Questions", a World Health Organisation Publication (Timmermans, 2001), defines bioprospecting as the systematic search for and development of new sources of chemical compounds, genes, micro-organisms, macro-organisms, and other valuable products from nature.

Four major phases of bioprospecting activity have been described by Leary (2007) as shown in Fig. 1. The phases range from sample collection, isolation, characterization to product (drug) development and commercialization. Bioprospecting does not only comprise of a provider and an acceptor but the entire process of bioprospecting involves various components including the owner(s) of marine genetic resources, the bioprospectors, research and development group (if separate from the bioprospector) and end product users. These components are highly interdependent on each other as well as on the genetic resource (Fig. 2).

It is noteworthy that bioprospecting in general has an inherent element of uncertainty with respect of the quantum of returns and also the protocols used for bioprospecting are complex as well as time and cost intensive. Therefore, return on investment is a major point of consideration by the pharmaceutical companies for investing in marine research and development. The pharmaceutical companies tend to protect the identified compounds of interest and the collected information under proprietary regime because of the huge investments involved in explorations, collection of sample and screening of the compounds which may every time require optimization of new protocol. Drugs of pharmaceutical interest derived from the marine organisms are protected through various tools of intellectual property law but mainly via patent regime. It has been observed that in the recent times there is a sharp rise in the patenting of products and processes derived from marine bioresources such as sponges, jelly fish, seaweeds (Demunshi and Chugh, 2009; Siswandi, 2013). Interestingly, a close relation exists between innovations (patents) and marine traditional knowledge (Vierros et al., 2010). The marine indigenous communities depend on marine resources for their livelihood, food and medicine. The wealth of marine traditional knowledge developed by these communities has been passed from one generation to next and both the communities as well as their surrounding marine habitat survive in a sustainable manner thereby preserving the marine ecosystem (Demunshi and Chugh, 2010). The marine traditional knowledge also exists in the alternative traditional medicine systems of marine biodiversity rich countries (Alves, 2006).

Pharmaceutical companies besides conducting expeditions to identify novel bioresources for pharmaceutical compounds, also often base their exploration for a marine organism of pharmaceutical interest based on the traditional knowledge developed by the indigenous communities. It is primarily opted by the pharmaceutical companies as it saves time for random screening and investment for collating basal information such as habitat, time of reproduction, population density etc. However, there are many instances of biopiracy of marine life and associated traditional knowledge as the access to marine genetic resources has been without the knowledge of the State or the indigenous marine communities (Singh, 2000). The communities have been deprived of fair and equitable sharing of the benefits arising from the commercialization of their knowledge. According to Global Industry Analysts, marine bioresources were expected to give rise to 'marine biotechnology' products worth over $3.75 bn by 2012, particularly functional ingredients for nutritionals, cosmetics and pharmaceuticals (Meredith, 2010) and while according to another market report by TechNavio, the marine biotech market is anticipated to grow at a CAGR of 3.82% over the period 2012–2016 (Global Marine Biotech Market, 2012–2016).

Thus, with ever increasing population, there is augmentation in demand and a niche market for bio based products such as bio-drugs, alternative fuels supporting clean technologies and sustainable development. The ever increasing demand would in turn enhance marine bioprospecting activities. Thereby, raising the urgent need for developing mechanisms such