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Intellectual Property Rights:

A Perspective in Marine Fisheries and Mariculture

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भाकृ अनुप
ICAR

Central Marine Fisheries Research Institute

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A Perspective in Marine Fisheries and Mariculture

A Publication of ITMU

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Intellectual Property Rights:
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FOREWARD

Earth's surface covers more than two-thirds water with five large oceans, which offer an ecosystem for the growth of various forms of lives with unique properties, which are generally not present in the terrestrial ecosystem. Historically marine ecosystem and marine biodiversity benefited mankind through direct and indirect economic benefits and industrial means. However, there is a high degree of representation of terrestrial-derived bioproducts, but the number of patents that have found their way into IP protection from marine origin is thus far small.

Intellectual property rights, which connote the rights available for the protection and exploitation of technology for the benefit of patentee, society, and government, occupy an important place in today's world. IP is generally categorized into industrial property, which concern patents, trademarks, designs and copyrights. Intellectual property safeguards the rights of an inventor in his invention, and at the same time facilitates social and economic growth by providing an impetus to the advancement of science and technology. Consequent to India becoming signatory to TRIPS in 1998, and with the latest amendments taking effect from 2006, the TRIPS compliant IP laws in India created the best investment opportunities and conducive environment for protection of valuable inventions and IP rights in marine fisheries and mariculture.

Central Marine Fisheries Research Institute (CMFRI) pioneered in shaping a number of IP protected technologies, which are of direct or indirect benefits to the society and mankind. Design, development and propagation of open sea cage device for cultivating marine fishes along the coastline of India, cutting edge mariculture technologies of food fishes such as cobia *(Rachycentron canadum),* silver pompano *(Trachynotus blochii)* and pearl spot *(Etroplus suratensis*) are some of the success stories of marine fisheries and CMFRI. The mariculture in open sea cage device will expand a new mariculture space in future and contribute immensely towards the Blue Revolution in India. The breakthrough of cobia and pompano breeding is considered as a milestone towards the development of foodfish mariculture in the country.

Our institute achieved the rare feat of joining the elite group of countries (US and Australia) engaged in satellite tracking of yellowfin tuna *(Thunnus albacares)* with pop up satellite tagging of this species in oceanic waters. CMFRI showed the way of land-based culturing of pearl oyster in marine body, open sea green mussel farming, edible oyster farming, hatchery technology for production of clam, sea horse, ornamental fish, mass scale spat production of green mussel, fish aggregating devices (FAD), production process for sea cucumber *Holothuria scabra* and *Holothuria spinifera* seeds or fingerlings, resource management of the Indian sacred chank, propagation of soft coral *Sinularia kavarattiensis,* polyunsaturated fatty acid enriched formulation, phytase from mangrore associated bacteria, Cadalmin™ Varna and Cadalmin™ Silo fish feed, gene mining technologies for various important traits, cost effective and rapid duplex PCR kit for early detection of white spot syndrome virus of shrimp, which are of direct use of the fish farming communities.

Marine organisms have various potential applications in the area of human health. This has more to do with the relative infancy of marine bioprospecting. In the process of harnessing high value bioactive molecules from marine organisms, CMFRI could able to successfully isolate high value compounds and developed a number of products for use as nutraceuticals. A patented product Cadalmin™ Green Mussel extract (Cadalmin™ GMe) containing anti-inflammatory principles from *Perna viridis* to combat joint pain, arthritis/ inflammatory diseases has been developed by CMFRI as an effective green alternative to the synthetic drugs available in the market. Cadalmin™ Green Algal extract (Cadalmin™ GAe) is another addition to the pipeline of the nutraceuticals developed by CMFRI as a natural remady to chronic joint pain and arthritis. Cadalmin™ GAe contains 100% natural and vegetarian marine bioactive antiinflammatory ingredients, which have been extracted from a blend of marine macroalgae or seaweeds with an ecofriendly "green" technology. The products of our institute are released under the Trademark of Cadalmin in classes 31 and 35.

Intellectual property is an important and effective policy instrument to a wide range of socio-economic and technological concern. It is to be remembered that the possession of a patent not only confers certain monopoly rights and privileges of the patented article, but certain obligations and duties also. Working of patents for commercialization of IP-protected technologies of CMFRI to yield the benefit of the patented inventions for mankind must be our primary objective.

This publication highlights the potential role of marine fisheries and marine ecosystem with respect to intellectual property management and their know-how's. There is lack of database on the intellectual properties in marine fisheries and mariculture. Thus, there is need to document the valuable technologies from the sea. This book describes the role of marine fishery resources as an emerging sector leading to intellectual property, and provides valuable information for effective IP management of the scientists, administrators, and research scholars in this sector.

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January 2013

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CONTENTS

The open sea cages developed and propagated by CMFRI are used for cultivating marine fishes, and may be used in domestic and export oriented marine sea farming in cages. The invention entitled "A Device for Breeding and Culturing Marine Fish in Open Sea (Indian Patent Application No. 31/CHE/2010)" describes a cage culture device for open sea fish farming in this direction. The system is eco-friendly without any human intervention and a higher survival of cultured fishes of above 75% was achieved and sustained. The mariculture in open sea cage deviced under the present invention will expand a new mariculture space, thereby the mariculture scale can be expanded greatly; simultaneously the self-pollution of mariculture can be solved. About 56 cages have been deployed by CMFRI throughout the coastline of India.

CHAPTER 1

Intellectual Property Rights: An Introduction

Central Marine Fisheries Research Institute pioneered in the cutting edge mariculture technologies of food fishes such as cobia (Rachycentron canadum), silver pompano (Trachynotus blochii) and pearl spot (Etroplus suratensis). Cobia (Rachycentron canadum) was bred for the first time in India at CMFRI during February, 2010. Their F_1 generations have reached a size of 10-15 kg at Mandapam and Karwar. This is a breakthrough of marine foodfish breeding in India.

Intellectual Property Rights - An Introduction

1
CHAPTER

Introduction

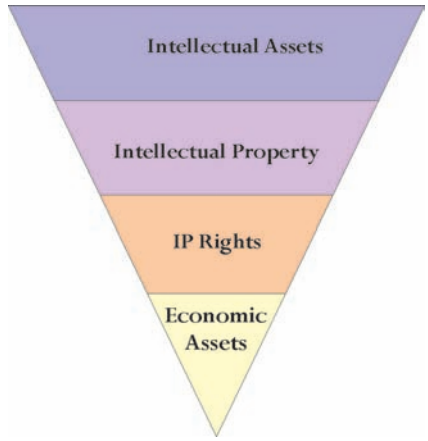
The concept of intellectual property would have aroused with the first invention. Nevertheless, with the industrial boom arose the need to protect the invention from being copied without the inventor's consent. With the development of new technologies a balance between the private rights and public interests need to be implemented, and there born the intellectual property system. The first intellectual property system came in from the West with the industrial development for the past four centuries. Through these years, the Intellectual Property Rights (IPR) has converted from feudal power to people's private rights.

The First Intellectual Property Rights System in the World

In the 13th century (1449), the King of Britain (Henry VI) granted a license to the inventor (Flemish-born John of Utynam) a patent, which leads to the patent law. The Republic of Venice city constituted the first world's patent law in 1474 with a venetion statute. During a long period of time, the framework of the intellectual property system, which include of copyright, patent and trademark rights for the main modules, has established in the 19th century. Through a number of international conventions, the intellectual property system had come to the international stage.

How Intellectual Assets can be converted to Economic Assets?

The dynamic and complex law sector of IPR has evolved with industrialization. As the human intelligence and creations transferred as technology, the means of legal protection evolved, especially to proceed into commercialization. The IP rights give both recognition and monetary benefits to the owner.



What is Intellectual Property Right (IPR)?

According to World Trade Organisation (WTO), Intellectual Property Rights are the rights given to persons over the creations of their minds. They usually give the creators an exclusive right over the use of their creations for a certain period.

How IPR has originated?

- International exhibition of inventions was held in Vienna in 1873 where many countries refused to display their inventions due to lack of legal protection.
- The Congress of Vienna (1873) was held for patent reforms.
- International Congress on Industrial Property was held in Paris (1878).
- International Conference in Paris in 1880, and concluded in 1883 during the Paris Convention (Protection of Industrial Property).
- Berne Convention was held in 1886 for international agreement to govern copyright (Literary and Art).
- In 1893, the Bureau of Paris Convention and Berne Convention united to form an international organization called as the United International Bureaux for the Protection of Intellectual Property (best known by its French acronym BIRPI), the predecessor of the World Intellectual Property Organization (WIPO) of today. In 1970, BIRPI became WIPO, which has undergone structural and administrative reforms and acquired a secretariat answerable to the Member States.
- Budapest Treaty: The Budapest Treaty on the international recognition of the deposit of microorganisms for the purpose of patent procedure, which is a special agreement under Article 19 of the Paris Convention, entered into force on August 9, 1980.
- Madrid System: The system of international registration of marks is governed by two treaties: the Madrid Agreement concerning the international registration of marks (1891), and the Protocol relation to Madrid Agreement, which was adopted in 1989, and entered into force on December 1, 1995, and came into operation on April 1, 1996.
- Strasbourg Agreement: The Strasbourg Agreement is known as the International Patent Classification (IPC), also known as the IPC Agreement. This agreement includes a uniform system of patent classification aimed at reducing problems associated with the diverse national patent classification systems, and to facilitate the retrieval and referral of patent documents.

The World Intellectual Property Organization (WIPO) *(French: Organisation mondiale de la propriete intellectuelle or OMPI)* is one of the specialized agencies of the United Nations. WIPO was created in 1967 with the stated purpose "to encourage creative activity, and to promote the protection of intellectual property throughout the world". WIPO currently has 184 member states, administers 23 international treaties, and is headquartered in Geneva, Switzerland. Vatican City and almost all the UN members are members of the WIPO. Non-participating states are Kiribati, Marshall Islands, Micronesia, Nauru, Palau, the entities of Palestinian Authority, Sahrawi Republic, Solomon Islands, Taiwan, Timor-Leste, Tuvalu and Vanuatu.

WIPO members

WIPO Headquarters in Geneva

(Source: Dedicated website: http://www.search.com/reference/World_Intellectual_Property_Organization)

What is Paris Convention?

The Paris Convention is an international convention for promoting trade among the member countries, devised to facilitate protection of industrial property simultaneously in the member countries without any loss in the priority date. All the member countries provide national treatment to all the applications from the other member countries for protection of industrial property rights. The Convention was first signed in 1883. Since then, the Convention has been revised several times, in 1900 at Brussels, in 1911 at Washington, in 1925 at The Hague, in 1934 at London, in 1958 at Lisbon, and in 1967 at Stockholm. The last amendment took place in 1979. India became a member of the Paris Convention on December 7, 1998.

The principal features of the Paris Convention

- National treatment
- Right of priority
- Independence of patents
- Parallel importation

National treatment is essential to provide equal treatment to applications from member countries, in a given member country and not to differentiate between the nationals of various countries and nationals of the other countries for the purpose of grant, and protection of industrial property as decided in the Paris Convention. For example, a national of country 'A' applies for grant of a patent in India. According to the Paris Convention, the Indian Patent Office shall apply the same norms and rules, to the applicant from 'A', as applicable to an Indian applicant, for granting a patent. Similarly the applicant from 'A' shall have the same protection after grant and identical legal remedies against any infringement shall be available to the applicant provided the conditions and formalities imposed upon Indians are complied with. No requirement as to domicile or establishment in the country where protection is claimed may be imposed.

General Agreement on Tariffs and Trade (GATT, 1949-1993) and Trade-Related Aspects of Intellectual Property Rights (TRIPS)

GATT was primarily formed during 1949 to provide the rules for international trading system, and protection against false indication and unfair competition.

- GATT was transformed as WTO in 1995. The last and largest GATT round, was popularly termed as Uruguay Round (from 1986 to 1994).
- Uruguay Round led to the formation of World Trade Organisation (WTO) and Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1995).

Key Features of TRIPS Agreement

The TRIPS Agreement is part of the "single undertaking" resulting from the Uruguay Round negotiations. This implies that the TRIPS Agreement applies to all WTO members, mandatorily. It also means that the provisions of TRIPS agreement introduced intellectual property rules into

the multilateral trading system for the first time and laid down minimum standards for protection and enforcement of intellectual property rights in the member countries. WTO Members can adopt higher standards of protection if they deem fit. The second set of obligations stipulates that the Members are free to determine the 'appropriate method' for implementing the Agreement within 'their own legal system and practice'.

WIPO had undergone a cooperation agreement with WTO in 1996 to demonstrate the importance of intellectual property rights in the management of globalized trade.

At the end of the Uruguay Round of the GATT in 1994, the TRIPS agreement was implemented to regulate standards of intellectual property regulations in WTO member countries. The Uruguay Round introduced IP rights into the multilateral trading system for the first time through a set of comprehensive disciplines. Being a member of the WTO and a signatory to the TRIPS agreement, it is compulsory for India to formulate its IP regulations to comply with the TRIPS agreement. The TRIPS Agreement is subject to WTO dispute settlement mechanism, which is contained in the Dispute Settlement Understanding ("Understanding on Rules and Procedures Governing the Settlement of Disputes", TRIPS) (Grain, 1998).

TRIPS constituted Annexure 1C of the Marrakesh Agreement (Marrakesh Agreement was the final act of the Uruguay Round of GATT negotiations concluded in Marrakesh, Morocco and was effective since 1st January 1995), which established the WTO. TRIPS is intended to maximize the contribution of IP systems to economic growth through accelerating trade and investment.

TRIPS Agreement Covers Five Broad Issues

- How basic principles of the trading system and other international IP agreements should be applied to improve trade?
- How to give adequate protection to IP rights?
- How countries should enforce those rights adequately in their own territories?
- How to settle disputes on IP between members of the WTO?
- Special transitional arrangements during the period when the new system is being introduced.

Amendments introduced in the Indian Patents Act to make it TRIPS-compatible

India's commitment to fully implement the Agreement on TRIPS required three sets of amendments to the country's Patents Act. While developing countries, in general, were allowed to make their patent laws TRIPS compliant through an amendment (introduced by January 1, 2000), countries like India, which had process patent regime covering pharmaceuticals and agricultural chemicals, enjoyed a longer transition period before they were required to introduce product patents from January 1, 2005. The longer transition period, however, came with a set of conditions elaborated in Articles 70.8 and 70.9 of the TRIPS Agreement (as "Transitional Arrangements"). Article 70.8 of the TRIPS Agreement required India to provide 'a means' by which product patent applications can be filed from January 1, 1995. If the product figuring in these applications were granted a patent in any of the WTO member countries and the products had obtained marketing approval in any of the WTO Member countries, then, according to Article 70.9, five years exclusive marketing rights (EMRs) had to be granted by India before the patent on the

product was either granted or rejected in India. The first amendment of the Patents Act 1970 introduced the requirements under the transitional arrangements through Section 5(2) (India, WTO and Trade Issues: Newsletter of Centre for WTO Studies, 2008). On January 1, 2000, a Second Amendment was introduced to bring the Patents Act in conformity with all the substantive provisions of the TRIPS Agreement, barring those related to the introduction of product patents. The key issues included in the Second Amendment were, redefining patentable subject matter, extension of the term of patent protection to 20 years and amending the compulsory licensing system. A third amendment was introduced in January 1, 2005 to introduce product patent regime in areas, including pharmaceuticals that were hitherto covered by process patents. Although the Third Amendment had a narrow remit, the government used the opportunity to undertake yet another review of the Patents Act. Among the major issues included in the Third Amendment were provisions relating to opposition to the grant of patents.

The IPRs covered by the TRIPS Agreement are

- Copyright and related rights (i.e., the rights of performers, producers of sound recordings and broadcasting organizations)
- Trademarks, including service marks Geographical Indications including appellations of origin
- Industrial designs
- Patents including the protection of new varieties of plants
- Layout-designs (topographies) of integrated circuits
- Undisclosed information, including trade secrets and test data

Why IPR?

Intellectual property rights or IPRs are rights given to people over the creations of their minds. These rights are given by society through the State as an incentive to produce and disseminate ideas and expressions that will benefit society as a whole. Unlike Fundamental Rights of citizens which are guaranteed by the Constitution of a country, IPRs are statutory rights enacted by the lawmaking authority in a country.

- IPR are granted because they are believed to stimulate discoveries and inventions.
- Gives monopoly of the inventor over the commercial exploitation of the idea for a fixed period of time.
- Protect the invention from unlawful imitation and competition.
- Provides incentive to the inventor.
- Enables promotion/improvement of the invention, and their commercial exploitation.

According to Indian Patent Office's Manual

- 'Discovery' adds to the amount of human knowledge by disclosing something, which has not been seen before.
- 'Invention' adds to the human knowledge by suggesting an act, to be done.
- An invention could be a new composition, device or process, either derived from a pre-existing idea or independently conceived.

What are the types of IP Protection?

Intellectual property rights are divided into three main areas:

(1) Copyright and Rights Related to Copyright

- The rights applied to authors of literary, dramatic and artistic works (such as books, publications and other writings, musical compositions, paintings, sculpture, computer programs and films).
- The main social purpose of protection of copyright and related rights is to encourage and reward creative works.
- The agreement says performers must also have the right to prevent unauthorized recording, reproduction and broadcast of live performances for no less than 50 years.
- Computer programs are protected as literary works and outline how databases should be protected.
- CMFRI has copyright on scientific publications (books, journal, bulletin and special publications).

Copyright of Indian Journal of Fisheries: Central Marine Fisheries Research Institute

2) Industrial Property

Covers areas that have industrial applications. Industrial property includes:

- Trademarks (distinguish the goods or services of one undertaking from those of other undertakings), and geographical indications (identify a good as originating in a place where a given characteristic of the good is essentially attributable to its geographical origin).
- The trademarke protection may last indefinitely, provided the sign in question continues to be distinctive.
- Patents, industrial designs and trade secrets are the industrial properties used to stimulate innovation, design and the creation of technologies. The protection under these categories is usually given for a finite term (typically 20 years in the case of patents).

Trademarks

- Trademarks are any sign or combination of signs capable of distinguishing the goods or services of one undertaking from those of the other.
- Service marks must be protected in the same way as trademarks used for goods.
- Marks that have become well known in a particular country enjoy additional protection.
- TRIPS Agreement provides initial registration and each renewal for a term not less than 7 years and shall be renewable indefinitely.
- CMFRI has trademarks on "Preparation and filing of trademark registration application of mark Cadalmin" under class 31 (Food for fish, seeds) and "Preparation and filing of trademark registration application of mark Cadalmin" under class 35 (Trading and Marketing).

Trademark

Cadalmin™ is the Trademark of Central Marine Fisheries Research Institute

Cadalmin™ GMe, Cadalmin™ GAe, and Cadalmin™ Varna are the three products released under the Trademark of Central Marine Fisheries Research Institute.

Cadalmin™ GMe contains 100% natural marine bioactive anti-inflammatory ingredients extracted from green mussel *Perna viridis*. The product is effective to combat chronic joint pain, arthritis/ inflammatory diseases.

Cadalmin™ GAe is an anti-arthritic and 100% vegetarian nutraceutical from seaweeds or marine macroalgae.

Cadalmin ™ Varna is an indigenously produced dry formulated feed for marine ornamental fishes.

Geographical Indications

Identify a good as originating in the territory, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.

Like TM, GI is a form of IPR used in product marketing, represented in words, figures, graphics, diagrammatic presentations or any specific combination of these indications.

Some examples are as follows:-

- **Fruits and Nuts:** Jaffa orange, Nagpur orange, Alphonso mango, Chausa.
- **Aurvedic products:** Triphala, Chavanprash, Kalimoonch rice.
- **Beverages:** Rioja wine, Darjeeling tea, Brahmaputra valley tea, Nilgiri tea, Rubios tea.
- **Foodgrains:** Basmati rice, Pokkali rice, Arroz de Valencia rice.
- **Animal & meat products:** Jamunapari goat (paneer), Malbuner sausages.
- **Indigenous products:** Nannari sharbat from *Hemidesmus indicus*, Kokam juice from *Garcinia indica*, Buransh juice from *Rhododendron arboretum*.

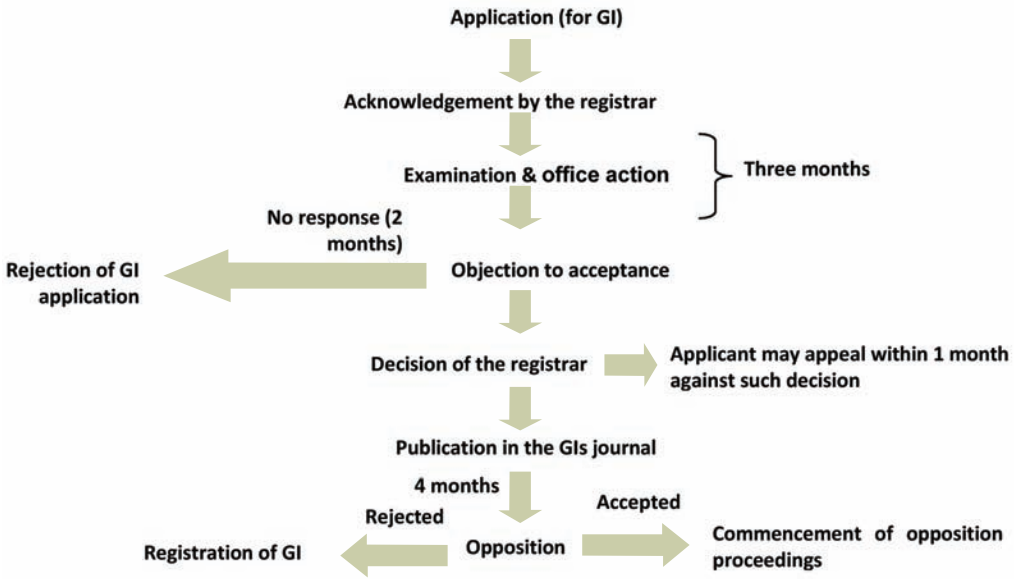
Difference between Trademarks and Geographical Indications

Trademarks identifies the products with the manufacturer with individual rights and can be assigned as well as licensed.

Geographical Indications identifies the products with the place of production or origin and has community rights. However GI cannot be assigned, transmitted or licensed.

Geographical Indication: Wine produced in a particular part of France.

Geographical Indications: Application to Grant



GI :
Combination of agroclimatic conditions, environment methods of cultivation/harvesting, and processing

Registration of GI (for 10 years and can be renewed successively for further period of 10 years) is based on

- Organization or authority established by or under the law
- Association of persons/producers

Geographical Indications

- A place name is used to identify a product.
- It says where the product is made, *viz.*, Nilgiri and Darjeeling tea.
- Identifies the product's special characteristics that are the result of the product's origins.

Industrial Designs

- Protected for at least 10 years.
- Owners of protected designs must be able to prevent the manufacture, sale or importation of articles bearing or embodying a design, which is a copy of the protected design.

Patents

- Patent protection is for at least 20 years.
- Patent protection is available for both products and processes.
- Governments can refuse to issue a patent for an invention if its commercial exploitation is prohibited for reasons of public order or morality.

(3) *Sui generis* Systems

A "*sui generis*" system is a Latin expression, simply means "one that is of its own kind". In this case it refers to the creation of a new national law or the establishment of international norms that would afford protection to intellectual property dealing with genetic resources or biodiversity and the biotechnology that might result. It also refers to a law that might protect creations, inventions, models, drawings, and designs, innovations contained in images, figures, symbols, petroglyphs, art, music, history and other traditional artistic expressions. The diversity of the subject matter is one of the reasons why a *sui generis* system is not advisable, but there are other reasons as well.

Different *sui generis* approaches following Seiler (1998) are as follows:

Intellectual Property Rights for Communities

This approach could be used to provide communities with IPRs for their informal innovations and biodiversity-related skills that cannot be protected by conventional IPR systems.

Community Intellectual Rights and Collective Rights

This strategy could be pursued to protect the rights of indigenous communities from being usurped by foreign interests. All biodiversity-related rights of local communities (farmers as well as indigenous peoples) are to be protected by adequate legislation, which the state has to abide by. The primary objective is to prevent biopiracy. It is not intended to be in full compliance with the TRIPS stipulations.

Modified Plant Variety Protection

This approach is grounded on the stipulations of the PVP system, as laid down in the UPOV conventions.

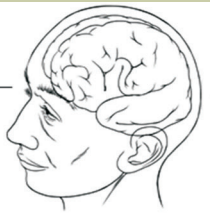
Comprehensive Biodiversity Legislation

In this case, an encompassing legislation deals with the protection and sustainable use of biodiversity. It aims at the definition of coherent policy measures in the national context. Aspects covered range from the question of access to genetic resources, biosafety, IPRs and communal rights.

Sectoral Community Rights Regime

Following this approach, a regulation system is designed especially to deal with the interests of local communities concerning specific categories of biodiversity. National legislation does not encompass all the biodiversity-related problems coherently but concentrates only on specific areas, which have to be protected, for instance medicinal

Types of Intellectual Property in a Capsule



Intellectual Property Rights (IPR)

Sui generis systems

Plant Breeders' Rights

Granted to breeders of new, distinct, uniform and stable plant varieties. They normally offer protection for at least fifteen years (counted from granting)

Integrated Circuits

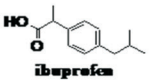
As the inventive step is often minimal and originality is the only requirement, the minimum period of protection under TRIPS is 10 years

Database Protection

Protection in respect of databases, preventing unauthorised use of data compilations, even if non-original

Industrial Property

Patents



ibuprofen

Patented as painkiller

Awarded for a fixed period of time (20 years minimum from filing date). As well as sufficient disclosure of the invention, there are three requirements (although details differ from country to country) that determine the patentability of an invention: novelty (new characteristics which are not "prior art"),9 non-obviousness (an inventive step not obvious to one skilled in the field), and utility (as used in the US) or industrial applicability (as used in the UK).

Industrial Designs

Protect the aesthetic aspects (shape, texture, pattern, colour) of an object, rather than the technical features for a minimum of 10 years

Trademarks

Distinctive of the proprietor so as to identify the proprietor's goods or services

Geographical Indications

Prevents unauthorized parties from using a protected GI for products not from that region or from misleading the public as to the true origin of the product

Trade Secrets

Consist of commercially valuable information about production methods, business plans, and clientele. Protected as long as they remain secret by laws which prevent acquisition by commercially unfair means and unauthorised disclosure

Artistic & Literary Property

Copyright

Copyright protection lasts for the life of the creator plus 50 years (70 years in the US and EU). It prevents unauthorised reproduction, public performance, recording, broadcasting, translation, or adaptation, and allows the collection of royalties for authorised use.

Computer programs are protected by copyrights, as software source and code have been defined as a literary expression

Thomas Alva Edison was an American inventor and businessman. He developed many devices that greatly influenced life around the world, including the phonograph, the motion picture camera, and a long-lasting, practical electric light bulb. In addition, he created the world's first industrial research laboratory. Dubbed "The Wizard of Menlo Park" (now Edison, New Jersey) by a newspaper reporter, he is often credited with the creation of the first industrial research laboratory. Edison is the fourth most prolific inventor in history, holding 1,093 US Patents in his name, as well as many patents in the United Kingdom, France, and Germany.

Edison's Menlo Park Laboratory in Greenfield Village at Henry Ford Museum in Dearborn, Michigan

Thomas Edison's first successful light bulb model, used in public demonstration at Menlo Park, December: U.S. Patent#223898: Electric-Lamp. Issued January 27, 1880

plants and the related indigenous knowledge systems.

Sui generis system is generlly divided under the following heads: -

- Plant breeders' rights.
- Database protection.
- Integrated circuits.

Integrated Circuit Layout Designs

The protection is available for at least 10 years. The examples under this category include:

- Semiconductor chips
- Layout-designs of ICs

Patents, industrial designs, integrated circuit designs, geographical indications and trademarks have to be registered in order to receive protection. Patents right, like all other rights conferred under this agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6. The registration includes a description of what is being protected the invention, design, brand name, logo, etc. This description is for public information.

What are the Rights of a Patentee Once the Patent is Granted?

A patentee enjoys the exclusive right to make and use the patented invention. The patentee also has the right to assign the patent, grant license, "or" otherwise deal with the patent, for any consideration. These rights are circumscribed by various conditions and limitations.

Article 28 of the TRIPS Agreement provides these exclusive rights as follows:

1. A patent shall confer on its owner the following exclusive rights:

- Where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product.
- Where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent, and to conclude licensing contracts.

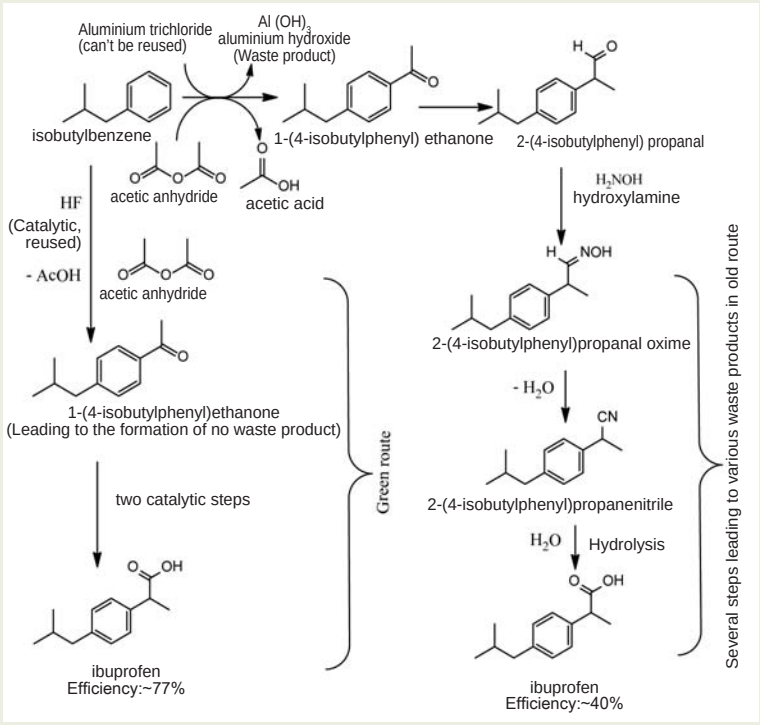
The literal meaning of the word 'patent' is 'open to the public, readily visible or intelligible'. The history of patents and patent laws is generally traced to Italy, to a Venetian Statute of 1474, which was issued by the Republic of Florence. The state issued a decree by which new and inventive devices, once they had been put into practice, had to be communicated to the Republic in order to obtain legal protection against potential infringers.

Product patent: It is granted when a new product has been invented by the person. The product so invented may either be more or less useful product than an already known product, or a new product altogether.

Process patent: It is granted for a new process of manufacturing an already known product or for manufacturing a new product, or for manufacturing more articles of the same product that is reducing the cost of the already known product. The example of process patent with respect to ifuprofen is illustrated under the process patent of green ibuprofen in the following page.

Process Patent: Green Ibuprofen

Ibuprofen is the main active ingredient in many over-the-counter painkillers. It was first prepared and patented in 1961. The original synthetic route involved six consecutive steps and had an overall atom efficiency of just 40% of the mass of all the atoms going into the process, 60% ended up in waste products. This route was used to manufacture the drug until the patent expired in 1984. If ibuprofen were still made in this way, more than 20,000 tonnes of waste would be generated annually. In the early 1990s, the BHC Company (now part of BASF) redesigned the synthetic route using many of the principles of green chemistry. The power of its approach is demonstrated by comparing the first steps of the two routes. The same chemical transformation occurs, but it is achieved in very different ways. Originally, Lewis acid $AlCl_3$ was required to promote the reaction. This generated $Al(OH)_3$ was filtered off as a cake of solid waste. To get a high-yielding reaction, the $AlCl_3$ was needed in excess, adding to the waste problem. But in the green route, HF is used to promote the reaction instead of $AlCl_3$. Because it is used as a catalyst, only a small amount of the acid is required; even better, it is recycled and used for making the next batch of product. In this way, a large amount of solid waste was eliminated from the process. The green route then adopts a synthetic strategy that is quite different from the original process, so that only two more steps are required (compared with five more needed in the original process). The overall efficiency of the green process increased to 77%. The green route thus produces more ibuprofen in less time and using less energy than the original process, which means cheaper products for the consumers with increased profits for the manufacturers.



Undisclosed Information and Trade Secrets

- Trade secrets and other types of "undisclosed information", which have commercial value, must be protected against breach of confidence.
- It is important to take reasonable steps to keep the information secret.
- Test data submitted to governments in order to obtain marketing approval for new pharmaceutical or agricultural chemicals to be protected against unfair commercial use.

Trade Secrets: Coco- Cola

A shiny red can that reads "Coca-Cola" and a whole list of ingredients: carbonated water, sugar, caramel, phosphoric acid, caffeine and natural flavorings. Coca-Cola is all about the magic of good taste & flavor - and apparently something highly secret. The natural flavorings are a unique blend of vegetable extracts and spices from around the world. Coca-Cola has never told what the 7 secret ingredients are, and this "Merchandise 7X" has remained the world's most famous trade secret since Coca-Cola's invention in 1886.

Frank M. Robinson, invented the name Coca-Cola, derived from its central ingredients. From that day on, there has always been a mystique about the "secret formula" of Coca-Cola. Folklore even said that the original beverage contained cocaine, at least until the "Pure Food and Drugs Act" was voted in 1906. Over the years, the Coke's attorneys have fought in court to protect Coca-Cola's secret formula. It's been said that the ingredient list is kept in a security vault in a bank in Atlanta, Georgia and only a few employees know the full recipe, and those employees are not allowed to fly on the same plane and cannot be left alone with strangers while they are together. Over the years, Coca-Cola's secret formula has been the subject of books, speculation and marketing (dedicated website: http://coca-cola-art.com.

IPR-Indian Context

The development of the IPR legislation in our country has been in parallel with the international scenario.

The sequential events of IPR legislation in India are illustrated below:

Indian Patents and Designs Act 1911

↓

A new Patent Bill in 1953

↓

The Act relating to Patent Rights- 1856

↓

Amended according to the British Patent Law (1852) and re-enacted in 1859

↓

Indian Patents Act – 1970

↓

Through several revisions

Patents (Amendment) Act of 2005

The monopoly granted to the inventor was known as "exclusive privileges".

What is the term of a patent? Once the patent is granted, do we need to renew it?

The term of a patent in India is 20 years from the date of filing. However, for patents granted pursuant to applications filed under the PCT, the term of 20 years begins from the international filing date. Yes, patents must be renewed. Maintenance/renewal fees are payable every year. The first renewal fee is payable at the end of the second year from the date of the patent. Renewal fees for any succeeding year must be paid before the end of that year. Renewal fees are not payable prior to grant; any annuties accrued prior to grant will be payable on grant.

The patent system involves the balancing of competing interests. While patent holders seek monopoly rights to make, sell, and license the patented invention towards maximizing their profits, many consider this as detrimental to the interests of society as patentees have the discretion of charging their own prices for their products. While these misgivings might to true to an extent, in reality the society's interests are protected rather than derided by the patent system. As the inventions for which patents are granted are accompanied by an enabling disclosure, competitors often use this information to produce improved products and patent them. Their improved products being also accompanied by enabling disclosure, provides the necessary base for further improvements. Thus consumers benefit as the patent system automatically leads to an increased choice in the market and patent holders benefit as they can focus their energies on providing new and improved products based on the consumers' preferences.

IPR Legislations of India

- The Copyrights Act-1957(amended in 1983, 1984, 1992, 1994 and 1999 along with Patents Rules 1958 and the International Copyright Order, 1999,2000 (Copyright Act).
- The Geographical Indications of Goods (Registration and the Protection) Act-1999 along with Rules 2002 (GI Act).
- Trademarks Act -1999.
- The Designs Act - 2000 along with Rules 2001 (Designs Act).
- The Semiconductor Integrated Circuits Layout-Design Act- 2000 (Rules 2001-IC Layout- Design Act).
- The Protection of Plant Varieties and Farmers' Rights Act, 2001 (Rules 2003- PPV&FR Act).

IPR in Life Form

IPR turned out to be significant after the TRIPS Agreement, being a multilateral agreement among the parties; the execution of the instruments of this agreement is international, while the IPR, as of today, remains the domain of national instruments. According to TRIPS, patenting the life form is inevitable while national instruments do not allow such step.

Life forms are not patentable in India

- Plants and animals in whole or any part (seed varieties).
- Biological processes for the production or propagation of plants and animals.
- Cells and cell lines.
- Cell organelles like mitochondria and genes.

Patents in Force by Origin

The phrase "Patents in Force" simply means the number of patents currently valid. Since patents are usually valid for about 20 years, this is a longer-term indicator of innovation, and a possible control for short-term trends in invention or investment that might skew other innovation indicators. WIPO publishes data on both the "destination" and "origin" of patents in force. Destination is more an indicator of the relative importance of patent offices, since it shows how many patents have been put in force by that patent office. It is also an extension of how many applications the patent office receives. Origin, on the other hand, shows how many patents there are in force around the world that came from a given country, regardless of where they were filed and approved.

How Patent Benefits

The Patentee

The patent law recognizes the exclusive right of a patentee by law to gain commercial advantage out of his invention with an idea to encourage inventors to invest their intellectual knowledge, knowing that no one else would be able to copy their inventions for a certain period (20 years) (Wadhera, 2001; Bentham, 1952). Patents provide the necessary incentive for inventors to undertake capital intensive projects knowing that they will receive the exclusive rights to profit from their inventions once they secure patents in respect of the inventions.

The Society and the Nation

The best illustration of how a patent benefits the public by encouraging disclosure in return for a period of exclusivity is the "Xerox machine". Before the invention of that copier, copies had to be made using expensive and messy systems like photography, heat-sensitive paper, or mimeographs and ditto machines. That changed when a patent attorney came up with an electrostatic copying method. Because the patent attorney was the first to invent the technique, he received a patent giving him the exclusive right to practice the invention for 17 years (under the law at that time). By the time the patent expired, Xerox was an established company, and companies like IBM and Canon joined Xerox in building and marketing plain-paper copiers.

Where do Marine Fisheries Stand?

Marine fisheries is in need for strategic and proactive research based inventions to make marine fish capture technically sustainable, environmentally friendly, economically profitable and socially relevant. With the fast changing marine fisheries scenario and emergence of mariculture as an alternate approach for enhancing coastal fish production, the institute has tuned its mandate in consonance with the need of the time. The institute is also in the process of focusing on frontier areas of research such as mariculture, marine bioprospecting for high value molecules and/ nutraceuticals, biotechnology, bioinformatics, remote sensing, and climate change. The products of Central Marine Fisheries Research Institute are marketed under CMFRI brand Cadalmin™, for which Trade Mark approval has been obtained from the Government.

TRIPS and Intellectual Property Rights with Special Reference to Fisheries

The main objective of the TRIPS agreement is explained under Article 7 as "……..to provide protection and enforcement of IP rights, which should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological

knowledge and in a manner conducive to social and economic welfare and a balance of rights and obligations". According to Article 65, WTO members (including India) must ensure their laws meet the minimum standards laid down in the TRIPS agreement. IP Rights at a multilateral level have their genesis in the Paris Convention for the Protection of Industrial Property in 1883, which protected industrial property *i.e.* patents and trademarks. Through the TRIPS, the WTO makes it mandatory for all its member countries to follow basic minimum standards of IPR provided for under TRIPS and bring about a degree of harmonization of domestic laws in this field. The TRIPS agreement represents the existing global state of IPR standards and legally binds all its member countries. It is the only agreement amongst several multilateral agreements under WTO which have significant impacts on global trade (Maskus, 2000). TRIPS has a direct impact on agricultural and fisheries trade and development, particularly on biotechnology aspects (WIPO, 2009), and its impact on trade is comparatively more important for developing countries as fisheries is a significant stakeholder in India's GDP. The key element of the TRIPS agreement for the agricultural and fisheries sector is the requirement for WTO members to make patents available for any inventions in the sector. The most important article in the agreement when considering the agricultural (fisheries subject is included under agriculture) sector is Article 27, which read as follows:

Article 27: Patentable Subject Matter

- 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. 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.
- Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect …., 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.
- Members may also exclude from patentability of diagnostic, therapeutic and surgical methods for the treatment of humans or animals; plants and animals 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.

Conclusion

According to the TRIPS agreement India had to provide legal protection to farmers traditional knowledge (including that of fisheries) via patents or by an effective *sui generis* system or by both, by 2006. However, the agreement provides for each country to determine and adopt a suitable procedure to implement the provisions of the agreement within its legal system and practices. Developed countries like US and UK have adopted well-built IP regimes using strong

patent systems in fisheries and agriculture sector, in general. The main reason for developed countries to choose patents for protection is due to their technological capabilities and the immense financial benefits that a patent system is expected to generate (Holger, 2001). Whereas, developing countries like India has weak IPR regimes due to lack of financial and technical support. Most of the developing countries have faced several difficulties in protecting inventions related to fisheries, which mainly attribute to lack of strong rules and regulations. Biological resources including that from fisheries sector have not been registered or documented in most developing countries and with the globalization process, bio-diversity and the traditional knowledge, skills and technologies possessed by local farmers in developing these varieties are at stake. Global Multi-National Companies (MNCs) have engaged in bio-piracy of vital genetic resources and associated traditional knowledge found in developing countries to get patent rights for their own countries. In this process, the developing countries are continuously denied the benefits, which legitimately belong to them. The industrial property systems were set up centuries ago for inanimate objects and that too in formal systems of innovation. The time has come to revisit them. The emerging challenge is to look at the systems that will deal with animate objects (such as fishes).

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CMFRI showed the way of land-based culturing of pearl oyster in marine body, which is of direct use of the fish farming communities. The land-based tanks are provided with filtered seawater through a slow sand filtration device, wherein the seawater was supplemented with mixed phytoplankton as feed for pearl oysters, wherein the oysters are attached to stones. The present invention (Indian Patent Appl. No. 1543/ CHE/2009) optimized the nacre production and coating over the nucleus in uniform thickness, while optimally maintaining the color and quality.

CHAPTER 2

IPR Organizational Set Up in CMFRI

Central Marine Fisheries Research Institute has initiated aquaculture research on silver pompano (Trachynotus blochii) from 2008 and the first successful broodstock development, induced breeding and larval production is now successfully accomplished. It can be considered as a milestone towards the development of pompano aquaculture in the country. The farming of pompano can be successfully carried out in ponds, tanks and floating sea cages. The species is able to acclimatize and grow well even at a lower salinity of about 10ppt and hence it is suited for farming in the vast low saline and brackish waters of our country besides its potential for sea cage farming.

IPR Organizational Set Up in CMFRI

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CHAPTER

Introduction

Central Marine Fisheries Research Institute (CMFRI) was established by the Government of India under the Ministry of Agriculture in 1947 and subsequently transferred to the Indian Council of Agricultural Research (ICAR) in 1967. CMFRI is the nodal agency in India responsible for research support in marine fisheries development. The multidisciplinary approach of the institute to research in marine fisheries sector has led it to one of the premier institutes of its kind in the world.

Importance of Intellectual Property Management

Intellectual property gives professional recognition to scientists/innovators for the technology creation. Commercialization of IPR enabled technologies and other expertise, through public-private partnership, would lead to their accelerated and efficient transfer. The adoption of IP protected technologies by producers will lead to increase in productivity, production, farmers' income and employment. This in turn will uphold the national growth.

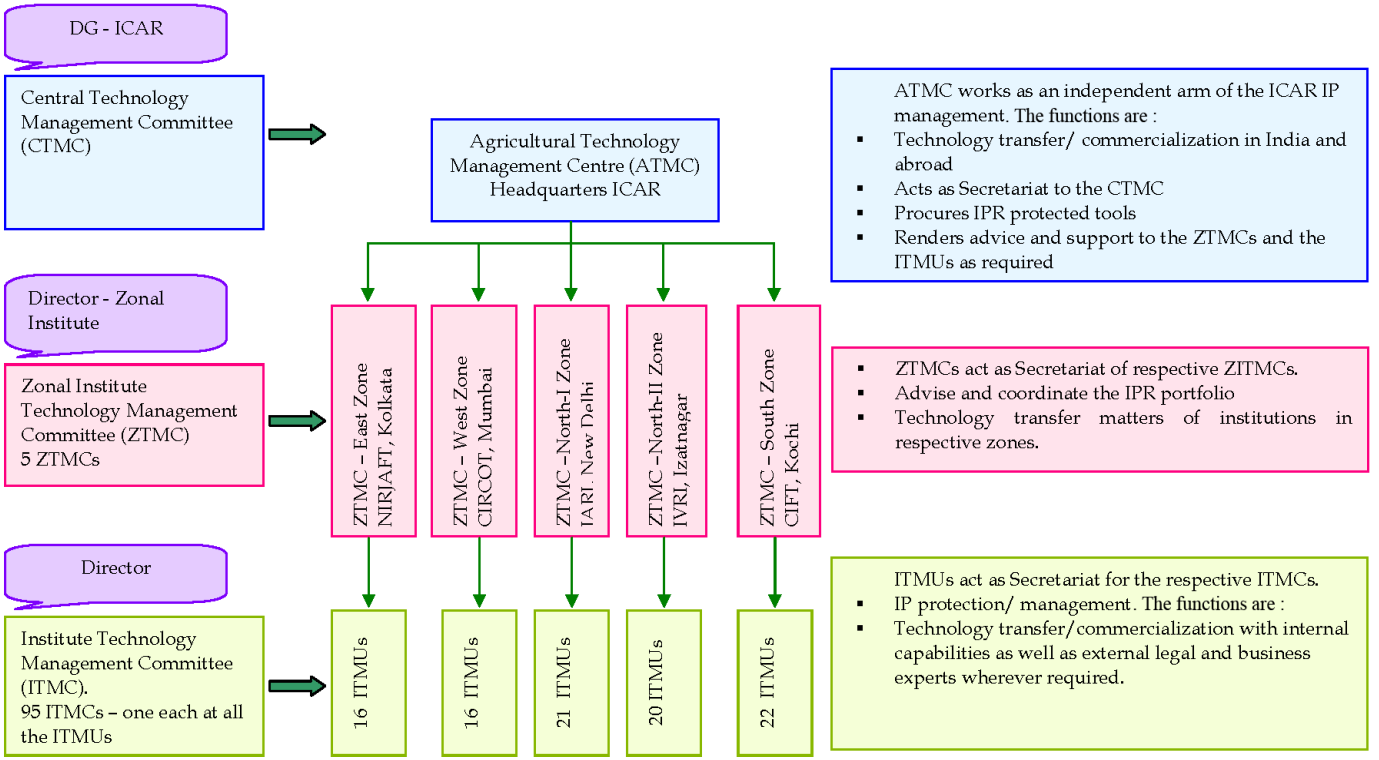
IPRs are Important for Marine Fisheries Sector

- Marine ecosphere constitutes a vast unexplored and untapped resource on Earth, and has immense potential to develop technologies for application to the benefit of mankind.
- Stimulates research, facilitates access to technology and promotes enterprise growth for the ultimate benefit of the society.
- Protect the intellectual wealth generated in CMFRI. The unprotected research results in the public domain can lead to unacknowledged use/ exploitation for commercial gains by other agencies both within the country and abroad.
- Research of CMFRI leading to mariculture, marine bioprospecting, biotechnology, fisheries management devices and fisheries products, are IP protectable, and the resources generated through commercialization of technologies would be useful for important gap filling requirements for research and development purposes.

ICAR is the apex body for planning, promoting, coordinating research and commercialization of technologies in the ICAR institutes. CMFRI being a part of ICAR needs to follow the norms that ICAR has developed. ICAR has devised a three tire institutional mechanism for the IP management in ICAR institutes with the expectation that the new IP regime will lead to a change in mindsets of the scientific community in conformity with thinking at the national and international levels. Each institute has a committee under Director to

Management of Intellectual Properties

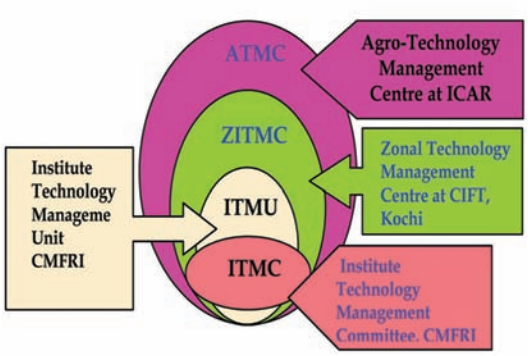
The three tier institutional mechanism for the IP management in ICAR institutes



manage the IP of concerned institute and take help and advice from zonal institute under which the institute falls. ICAR is the apex body and provides necessary advice, support and organize the zonal and institute level committees to manage the IP generated.

Management of Intellectual Properties in CMFRI

The IP management in ICAR institutes is based on the three tier institutional IP management mechanism mentioned above.



Institute Technology Management Committee (ITMC) and Institute Technology Management Unit (ITMU)

Under the Director of the institute, forms a decision-making body for IP related matters/ progress/concerns in CMFRI as Institute Technology Management Committee (ITMC). The ITMU acts as Secretariat for the ITMC. The Director of the institute is the Chairman of ITMC governing body, and the Scientist-in-Charge, ITMU officiates as Member Secretary of ITMC.

Organizational Set Up for IPR and Commercialization

Functions of ITMU in the Institute

The ITMU of CMFRI functions according to the ICAR IP guidelines.

- Help scientists to draft patent documents and claims.
- To carry out internal examination before filing patents.
- IP protection, maintenance and management.
- Patent filing; invite expert opinion from patent attorney/ IPR expert.
- ITMC duly records the reasons for acceptance/rejection of each patent proposal.
- Correction/ rectification/ updation of primary information.
- Technology transfer/ commercialization.
- Takes external legal and business advices wherever required.

Key Considerations Given by ITMU of CMFRI to Prioritize the Cutting-Edge Technologies

- National priorities relating to food security.
- Sustainable use of marine natural resources.
- Enhancing the income of small and marginal fish farmers.
- Protection of public sector research as defense mechanism to keep innovations in the public domain.
- IPR enabled technologies from marine resources to negotiate/ bargain access to strategic research tools and technology from the private sector.
- IP generated technologies from marine ecosphere as important gap filling requirements for research and development purposes.

Preliminary Steps to be Taken to Seek IP Protection in ICAR :

- All inventors shall assign the IP rights in their research results to ICAR.
- All applications shall be made in the name of "Indian Council of Agricultural Research" and patent applications to be filed by the Chairman ITMC (Director) to the Zonal Patent Office.
- Patent/IPR applications filed by ICAR, shall mention the names of all concerned scientists/innovators as True and First Inventors.
- Patent/IPR applications will be signed by the authorized signatory (Director of the concerned institution).
- Processing of all patent/copyright/other IPR applications and maintenance of IPR titles will be undertaken by ITMU as per the respective IPR laws and the guidelines framed by IP & TM Cell of ICAR.

Conclusions

CMFRI is instrumental to protect the cutting-edge technologies from marine ecosystem developed by the institute to comply with the conditions of the international agreements. A total of 17 patents have been filed during last 10 years. Cadalmin™ Green Mussel extract (Cadalmin™ GMe) effective to combat arthritic pain and inflammatory diseases developed by Central Marine Fisheries Research Institute has been commercialized. A MoU was signed with Accelerated Freeze Drying Company Pvt. Ltd., a FDA, ISO 22000 FSSC 22000:2011 certified flag Ship Company of Amalgam Group of Companies. The MoU is valid for a period of ten years, and as per ICAR guidelines. Some of the prominent technologies are ready to be commercialized. The ITMC and ITMU of CMFRI are proactive in this direction.

Suggested Readings

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CMFRI achieved the success of mass scale spat production of green mussel (Perna viridis) in Visakhapatnam hatchery. In this process green mussel has been spawned and larvae reared successfully to settlement of spat. Over 2 lakh spat have been successfully settled in the hatchery. The technology can be refined for transfer to end users.

CHAPTER 3

How to Apply for a Patent?

CMFRI has been successful in standardizing the hatchery technology for production of ornamental fishes particularly belonging to the genera Amphiprion and Premnas (family Pomacentridae and sub family Amphiprioninae) commonly known as "clown fishes or sea anemone fishes".

How to Apply for a Patent?

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CHAPTER

Introduction

A patent is a document, issued upon application by the government. A patent describes an invention and gives legal protection to the invention that it cannot be duplicated or copied without the authorization of the owner of the patent. The patent owner constitutes the power to take action against any person exploiting the patented invention in the country without the agreement of the patent owner. ICAR is the owner of any IP generated in ICAR institutes. Patent gives exclusive rights to sell, manufacture and market the product for a specified period, which is 20 years in India. After this patent term expires, any person can gather the information and reproduce the product as such or in a similar way to deliver the benefits of research and development for an indefinite period.

Criteria for Grant of a Patent

Patents provide property rights to inventions. An 'invention' may be defined as a novel idea which permits in practice the solution of a specific problem in a field of technology. Patents are available for any invention, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

Holly Trinity of Patent Law

Novelty of the Invention

An invention is considered as novel if it does not form a part of the global state of the art. Information appearing in any form of printed form such as magazines, technical journals, books, newspapers etc. constitutes the state of the art before filing a patent application in respect of the invention. If the invention is orally described or presented in a seminar/ conference novelty will cease to exist. It is mandatory to file a patent application before publishing a paper if the invention is patentable. Prior use of the invention in the country of interest before the filing date can spoil the novelty. Novelty is determined through extensive literature and patent searches. It should be realized that patent search is essential and critical for ascertaining novelty as most of the information reported in patent documents does not get published anywhere else. For an invention to be novel, modifications to the existing state of the art, process or product or both, can also be candidates for patents provided these were not earlier known. In a chemical process, for example, use of new reactants, use of a catalyst, new process conditions can lead to a patentable invention. In short the following points must be considered to qualify the invention as novel:

- The invention must be demonstrably different from publicly available ideas, inventions, or products (prior art).
- This does not mean that every aspect of an invention must be novel. For example, new uses/ improvements of known processes, machines, etc. are patentable.
- There should not be any prior disclosure of any information contained in the application for patent before priority date.

Usefulness

The invention must have some application or utility or be an improvement over existing products and/ or processes. No valid patent can be granted for an invention devoid of utility. The patent specification should spell out various uses and manner of practicing them, even if considered obvious. In short the following points must be considered to qualify the invention as useful:

- It is needed to specify whether the appraisal of industrial applicability of the invention is clearly made. If a process is claimed, the inventor need not to describe the use of the compound produced thereby. Nevertheless it would be safer to do so. But if a compound is claimed without spelling out its utility, the patent will be denied.
- Industrial application includes commercial or non-commercial utility, but it has nothing to do applicability with the commercial success.

Non-obviousness or Inventiveness

The invention cannot be obvious to a person of "ordinary skill" in the field. Non-obviousness usually is demonstrated by showing that practicing the invention yields surprising, and unexpected results. The following points must be considered to qualify the invention as non-obvious:

- The prior art should not point towards the invention implying that the practitioner of the subject matter could not have thought about the invention prior to filing of the patent application.
- Inventiveness cannot be decided on the material contained in unpublished patents.
- The complexity or the simplicity of an inventive step does not have any bearing on the grant of a patent. To state otherwise, a very simple invention can qualify for a patent. If there is an inventive step between the proposed patent and the prior art at that point of time, then an invention has taken place.

Venn diagram: Three essentials of a patent

Ownership of IP

ICAR will be the sole owner of IP generated from research work conducted in ICAR. When the research is under collaborative way, shared research facilities or on scientist-entrepreneurship for up-scaling/ commercial venture with the IP generated, the ownership will be shared depending on the share of scientific/technical input of the partner

How to Seek a Patent?

- The scientists/innovators who possess a patentable IP take(s) steps to submit patent through the ITMU of the institute.
- The interested scientist/innovator may arrange a meeting with the Chairman ITMC (Director) and disclose the patentable IP.

- The application for seeking patent accompanies an undertaking mentioning the novelty of invention, and the patent application to be routed through ITMU for Indian Patent application.
- The ITMU fix a confidential meeting with ITMC for taking further steps, and shall sign an undertaking to maintain confidentiality of the information.

Scientists shall not publish or disclose any information as any printed form on the patentable innovation before filing the application.

Disclosure implies the oral, written or electronic dissemination of the inventor to a person outside the institute.

The patent applications to be routed through ITMC of the institute and ATMC (ICAR) for PCT / international patent applications. The general guidelines are as follows:

Step 1. Scientists/innovators may submit the particulars: The Principal Investigator/ Project Leader (PI)/Scientists concerned shall provide the details about the invention including specification, claims and other particulars with due signatures of all Inventors/to the ITMU for writing the application. Besides, an undertaking covering the bonafides of the / deemed IP, including title, novelty, non obviousness/ inventiveness, and industrial applicability/ commercial usefulness shall also be produced.

Step 2. Internal screening: The ITMU takes steps to scrutinize (on internal basis) and process the cases before filing of patent applications.

Step 3. Correction/updation of information: The concerned inventor shall modify the application based on the comments/ suggestions of ITMU. It is possible to add/ delete/amend the patent application with the consent of ITMU, if it adds value to the patent application.

How to Write a Patent Document

ITMU may hire the services of empanelled patent attorneys for revising the patent document in the proper format before being submitted to the Regional Patent Office. All patent applications are filed in duplicate in Forms 1, 2 and 5 according to the Patent Act. The application shall contain the following points.

- Sufficient information on the innovation for the patent examiner to understand the invention.
- Distinct claims for the patentability of the innovation.
- How the provisions of non-patentable subject matter (sections 3 and 4 of the Patents Act, 1970) clearly ruled out?
- The specifications must meet the criteria of "sufficiency of disclosure".
- Reference of deposit has to be made in the patent specification for genetically engineered microorganisms. As of now, there is only one recognized depository in India under Budapest Treaty (Institute of Microbial Technology, IMTECH, Chandigarh).
- Commercial or non-commercial utility of the invention must be specified in the patent document.
- Classification of the invention should be made and the results of the novelty search must be carried out and reported in the patent document.

Application Fee

This head is mentioned in the First Schedule of the Patents Act under the column "for other than natural person(s)". The application fee can be paid at the time of filing the application or within one month of the date of filing (please refer Annex-I for details).

Provisional Specification

A provisional specification is usually filed to establish priority of the invention in case the disclosed invention is only at a conceptual stage and a delay is expected in submitting full and specific description of the invention. Although, a patent application accompanied with provisional specification does not confer any legal patent rights to the applicants, it is, however, a very important document to establish the earliest ownership of an invention. The provisional specification is a permanent and independent scientific cum legal document and no amendment is allowed in this. No patent is granted on the basis of a provisional specification. It has to be a followed by a complete specification for obtaining a patent for the said invention. Complete specification must be submitted within 12 months of filing the provisional specification. This period can be extended by 3 months. It is not necessary to file an application with provisional specification before the complete specification. An application with complete specification can be filed right at the first instance.

Complete Specification

It may be noted that a patent document is a techno-legal document and it has to be finalized in consultation with an attorney. Submission of complete specification is necessary to obtain a patent. Contents of a complete specification would include title of the invention, field to which the invention belongs, background of the invention including prior art giving drawbacks of the known inventions & practices, complete description of the invention along with experimental results, drawings etc. essential for understanding the invention, claims, which are statements, related to the invention on which legal proprietorship is being sought. Therefore the claims have to be drafted very carefully.

Fate of a patent application is decided on specification and claims

Provisional specification is the document drawn in a prescribed format (Form 2 of the Rules) with essential features of the invention. A provisional application is filed to secure the "Priority Date" for the invention. An Indian applicant/institute can file for patent application under whose jurisdiction the applicant resides. For non-residents the address for service in India determines the patent office for filing patent applications. Form 2 of a Patent Application document consists of prior art, reference, object of the inventions, detailed specifications, applications, drawing and claims. The date of filing provisional specification is the priority date. Indian patent is based on first to file system, where the date of filing the application is important. Hence, the provisional specification is advised in a broader terms. The complete specification should be submitted within 12 months of the date of filing provisional specification. Within this incubation period the inventor can go for further research and incorporate the results obtained (within the framework/ concept of provisional patent) during this period in the complete application.

Patent Filing Procedure

Filing of an application for a patent should be completed at the earliest possible date. An application filed with provisional

specification, disclosing the essence of the nature of the invention helps to register the priority by the applicant. Delay in filing an application may entail some risks like (i) other inventors might forestall the first inventor by applying for a patent for the said invention, and (ii) there may be either an inadvertent publication of the invention by the inventor himself/herself or by others independently of him/her. Publication of an invention in any form by the inventor before filing of a patent application would disqualify the invention to be patentable. The invention should be considered for publication after a patent application has been filed. Thus, it can be seen that there is no contradiction between publishing an inventive work and filing of patent application in respect of the invention.

The Patent Office Chennai
Intellectual Property Office Building
Industrial Estate Sidco
RMD Godown Area,
G.S.T. Road, Guindy,
Chennai-600032
Tamil Nadu

Territorial Jurisdiction of the South Indian States (Andhra Pradesh, Karnataka, Tamil Nadu, Kerala, Pondichery, and Lakshadweep) (Patent Office Branch is situated at Chennai)

Patent Office	Territorial Jurisdiction (States and Union Territories)
Mumbai	Gujarat, Maharashtra, Madhya Pradesh, Goa, Chhatisgarh, Daman & Diu, Dadra & Nagar Haveli
Chennai	Andhra Pradesh, Karnataka, Kerala, Tamil Nadu, Pondichery, Lakshadweep
Delhi	Haryana, Himachal Pradesh, Jammu & Kashmir, Punjab, Rajasthan, Uttar Pradesh, Uttranchal, NCT of Delhi, Chandigarh.
Kolkata	Rest of India.

Preliminary Steps to Seek a Patent

Electronic Filing

This is possible with the use of a Class III digital signature through the Patent Office's Website. This procedure requires specific custom-made internet browser with security settings, for registration. Fees can be electronically transferred at the end of the file upload, through one of two payment gateways. However, the electronic filing system is not yet very user-friendly and it could be challenging to complete the filing process correctly.

Filing on Hard Copy

This is the popular way of communicating with Indian Patent Office and requires payment through demand draft or bank pay order. Acknowledgement and filing reference number are only sent by mail and may take up to a month to be mailed to the applicant. In order to obtain an immediate acknowledgement it is currently necessary to file in person at the patent office. A filing receipt is usually issued over the counter. The office accepts submissions of scanned or printed versions of declaration of inventorship and power of attorney. The requirement to submit original signed copy within one month of filing was deleted in a 2006 amendment to Rule 6(1).

Documents Required for Filing an Application

- Application form is required to be submitted in triplicate.
- Provisional or complete specification to be sumitted in triplicate. If the provisional specification is filed it must be followed by complete specification within 12 months (15 months with extension).
- Drawing in triplicate (if necessary).
- Abstract of the invention (in triplicate).
- Information and undertaking listing the number, filing date and current status of each foreign patent application (in duplicate).
- Priority document (if priority date is claimed).
- Declaration of inventorship where provisional specification is followed by complete specification or in case of convention application.
- Power of attorney (if filed through Patent Agent).
- Fee in cash/by local cheque/by demand draft.

Types of Patent Applications (under the Patents Act, 1970)

Ordinary/Standard Application

- This is the most common type of application filed and does not refer to another application to claim priority.
- It may be made with provisional or complete specification.

PCT International Application

- Patent Cooperation Treaty (PCT) is an international filing system for patents entered into force in 1978. India is a member of PCT.
- India joined the PCT on December 7, 1998.
- The unified procedure for filing patent application under PCT grants an international filing date (priority date) in member countries.
- Later, the applicant can go to the national offices within 3 years without affecting the priority date.
- All activities related to PCT are coordinated by the World Intellectual Property Organization (WIPO) situated in Geneva.

- Indians can file PCT International Application either in Indian Patent office or in the WIPO.

In order to protect any invention in other countries, it is required to file an independent patent application in each country of interest; in some cases, within a stipulated time to obtain priority in these countries. Inventors of Contracting States of PCT on the other hand can simultaneously obtain priority for their inventions without having to file separate application in the countries of interest; thus saving the initial investments towards filing fees, translation etc. In addition the system provides much longer time for filing patent application in member countries. The time available under Paris Convention for securing priority in other countries is 12 months from the date of initial filing. Under the PCT, the time available could be as much as minimum 20 and maximum 31 months. The inventor could also opt for preliminary examination before filing in other countries to be doubly sure about the patentability of the invention. The patent office or any other office designated by each Contracting State becomes a receiving office for receiving PCT patent applications. These applications are referred to International Searching Authorities (ISA), which usually the patent offices, appointed to carry out the patent search on a global basis. In case the receiving office is also an ISA, a separate referral is not required.

Application for Patent of Addition

- An application for patent of addition is filed when there is a modification or addition of already patented invention or application, within the term.
- Separate renewal fee is not required for patent of addition.
- Can be made independent to avoid the expiry with the main patent.

Divisional Application

- When more than one invention is disclosed in main application, a divisional application can be filed.
- Separate applications are filed in the original application.
- Divisional Application gains priority date of the main application.

Maintenance of Patents

A patent has to be maintained by paying the maintenance fees every year. If the maintenance fees are not paid, the patent will cease to remain in force and the invention becomes open to public. Anyone can then utilize the patent without the danger of infringing the patent.

- ITMU of CMFRI has the mechanism to maintain the patents obtained following the guidelines framed by IP & TM Cell of ICAR.
- Initially pay patent renewal fee for five years.
- Depending on the commercialization potential the patent is renewed further by consulting with ITMC of the Institute.

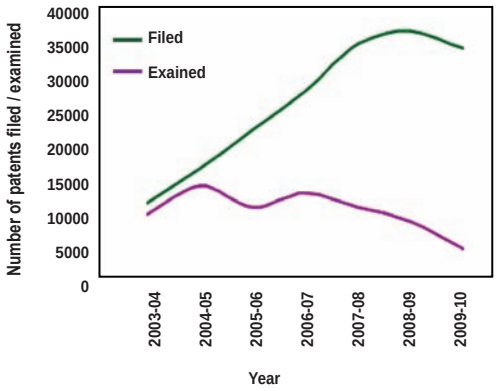
Examination and Publication

Patent applications are automatically published after an 18-month delay from the priority date, without payment of any additional fee. However, early publication can be requested on payment of Rs.10,000 /- (-200 USD, Rs. 2,500 or -50 USD for individual applicants), which result in publication of the bibliographic details and abstract of the application in the Patent Office Journal that is published weekly on every Friday on the Patent Office website. Full text including claims of published applications is accessible online via the "Application Status" button on the IPAIRS Website, but figures and tables are not available online. Alternatively, a copy of

each application of interest can be requested on payment of a fee of Rs. 4 per page at the appropriate patent office where the application was filed. The following points need to be noted regarding examination and publication of patent applied.

- All the applications for patent with complete specification are examined and a first examination report stating the objection(s) / comments is / are communicated to the applicant.
- Application/s is/are corrected according to the report within 15 months from the date of first examination report.
- When the objection(s)/comments are not fulfilled within the stipulated time, the application would be abandoned.
- When the application is found to be suitable for acceptance it is published in the gazette of India (Part III, Section 2). It is deemed laid open to the public on the date of publication in the gazette of India.
- The accepted application is published in the Patent Office Journal just after 18 months from the date of filing of the application or the date of priority, whichever is earlier.

The Indian Patent Office is currently experiencing a backlog of application to be examined. The number of applications filed, examined and the year-wise backlog for patent filings at the Indian Patent Office between 2003 and 2010 are shown in the following figure. The backlog numbers do not include the number of applications pending prior to 2003. From the filing data, the cumulative number of applications unexamined at the end of 2009-10 is estimated to be 110,515. As the diagram shows, there is a steady drop in the number of applications examined and a steady increase in the backlog for the period 2003-2010.



India patent office filing 2003-2010 (source: Gopakumar, A. 2012, http://wiki.piug.org)

Patent filings by the Indian applicants in every year are growing only with a rate of about 11.6%, where as foreign applicant filing growing at a rate of about 31.7%. The patent filed by the Indian firms lag behind substantially as compared to foreign counterparts. The trend in patent filing by the Indian companies is not good signal to advance our Indian economy (Source: Annual reports of the Indian Patent Office, 2008).

Opposition

Any person can oppose a patent before grant with evidence to object. Opposition must be filed within four months of publication. Extension of one month is available, but must be applied for before expiry of initial four months. The opposition to the grant of patent was summarized by The Economist as: '...inflames cupidity, excites fraud... begets disputes and quarrels between inventors, provokes endless lawsuits, makes men ruin themselves for the sake of getting the privilege of a patent, which merely fosters a delusion of greediness' (The Economist). Opposition to grant of patent rights is seen especially with regard to patenting of pharmaceutical products.

Grant or Sealing of Patent

When an application could meet requirements of PER and opposition, the patent is granted or sealed on payment of sealing fee within 6 months from the date of publication under section 11 A.

Patent rights are essentially territorial in nature and are protected only in a country (or countries), which, has (have) granted these rights. In other words, for obtaining patent rights in different countries one has to submit patent applications in all the countries of interest for grant of patents. This would entail payment of official fees and associated expenses, like the attorney fees, essential for obtaining patent rights in each country. However, there are some regional systems where by filing one application one could simultaneously obtain patents in the member countries of a regional system, such as European Patent Office.

Rights of Patentee

Patents issued by the Indian Patent Office confer upon the patent holder, an exclusive right, under which, no third party can exercise the patentee's right without the patentees consent. The rights conferred, in respect of a product patent, are the act of making, using, offering for sale, selling or importing for those purposes the patented product. The rights conferred, in respect of a process patent, are the act of using that process, using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India (vide Section 48 of the Patents Act 1970). In brief the rights of the patentee are as follows:

- A patent grant gives the patentee the exclusive right to prevent others from performing/using the product/process without authorization.
- The patentee can make or use the patented article or use the patented process.
- Patentee has the right to assign the patent, grant licenses under, or otherwise deal with it for any consideration.

Working of Patents

After an applicant obtains a patent or obtains a license to a patent in India, Patent Office Procedure calls for furnish a statement from the patentee/licensee every year regarding "*working of patents on a commercial scale*". The patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article" but "to make the benefit of the patented invention available at reasonably affordable prices to the public" (vide Section 83 (b) and (g) of the Patents Act, 1970). The patentee/ licensee needs to file a statement every year within three months of the end of each year regarding "working of patents on a commercial scale in India" (vide Section 146(2) of the Patents Act, 1970; Patents rule 131(2)) to be published through Patent Office Website. Any time after three years from date of sealing of a patent, application for compulsory license can be provided if reasonable requirements of public have not been met, patented invention is not available to public at a reasonably affordable price, and the patented invention is not worked in India on a commercial scale.

If the patentee is not interested in commercialization of the said invention, any person interested may make an application for a compulsory license after a period of 3 years from the grant of patent. Applicant's capability including risk taking, ability of the applicant to work the invention in public interest, nature of invention, time elapsed since sealing, measures taken by patentee to work the patent in India will be taken into account to grant compulsory license. In case of national emergency or other

circumstances of extreme urgency or public non commercial use or an establishment of a ground of anti competitive practices adopted by the patentee, the above conditions will not apply. A patentee must disclose the invention in a patent document for anyone to practice it after the expiry of the patent or practice it with the consent of the patent holder during the life of the patent. This is to drive manufacturing activity within India based on patented inventions, and to yield their benefits for mankind.

Is it Necessary to Show Working of a Patent after Grant?

Yes. Annual reports as to the extent of working, by patentees and licensees, are a statutory requirement and must be submitted by 31st March each year for the previous year ending 31st December.

Can a Patent be Restored Once it has Lapsed?

A patent, if lapsed due to the non-payment of renewal fees, may be revived by filing an application for restoration within one year of lapse.

The Requirements of Patent Filing

This is described under the following heads:

(1) Convention and National Phase Filing/ National Phase entry in India, and (2) Indian Patent

Convention and National Phase Filing

Pursuant to the Indian Patent Act convention application must be filed within 12 months of the earliest priority date and a national phase entry patent application must be filed within 31 months of the earliest priority date.

Documents and Information Required

Complete specification/ description of the invention (including claims and, where applicable, drawings) in the English language.

Section 8[1] details (*i.e.*, application number, filing date and name of the country) of any corresponding applications must be furnished to the Patent Office within six months of the date of filing of those applications.

- A copy of the PCT pamphlet and PCT application.
- A copy of the International Search Report (ISR) and/or International Preliminary Examination Report (IPER).
- Name, address and nationality of the Applicant(s) and the Inventor (s).
- Priority details (for national phase entry, if priority is claimed).
- In case of national phase entry- A copy of the PCT pamphlet and PCT application (as filed) and a copy of the International Search Report (ISR) and/or International Preliminary Examination Report (IPER).

Subsequently, in order to complete the formal filing requirements, the following information must be submitted at the Patent Office:

Power of Attorney (POA): The POA, in favour of an Indian Patent Attorney, can be filed at any time during the prosecution of the application. Where the applicant is a company, the stamp of the company, the complete name and designation of each signatory must be indicated below the signature. The POA should be filed preferably within three months of filing the application.

Priority Document: A certified priority document, either the original document or

a copy of the PCT notification concerning submission or transmittal of priority document *i.e.,* PCT/IB/304 (for national phase entry), is required to be submitted at the Patent Office. Where the priority document is not in English, a duly verified translation into English by the applicant (or the person authorized by him must be provided.

Assignment Document: The original assignment, certified/notarized, must be submitted within six months of the date of filing the application, as proof of the right to file the application in India.

Details of the patent applications filed in foreign countries: The application number, filing date and name of the country of any corresponding applications must be furnished to the Patent Office within six months of the date of filing of those applications.

Patent Cooperation Treaty (PCT) Applications: An applicant wishing to file an international patent application must comply with the procedural formalities laid down in the PCT. A PCT or National Phase Entry application can be filed within 31 months of the convention application.

India - Patent Filing Procedure

In India, the Patent filing procedure comprises four main steps.

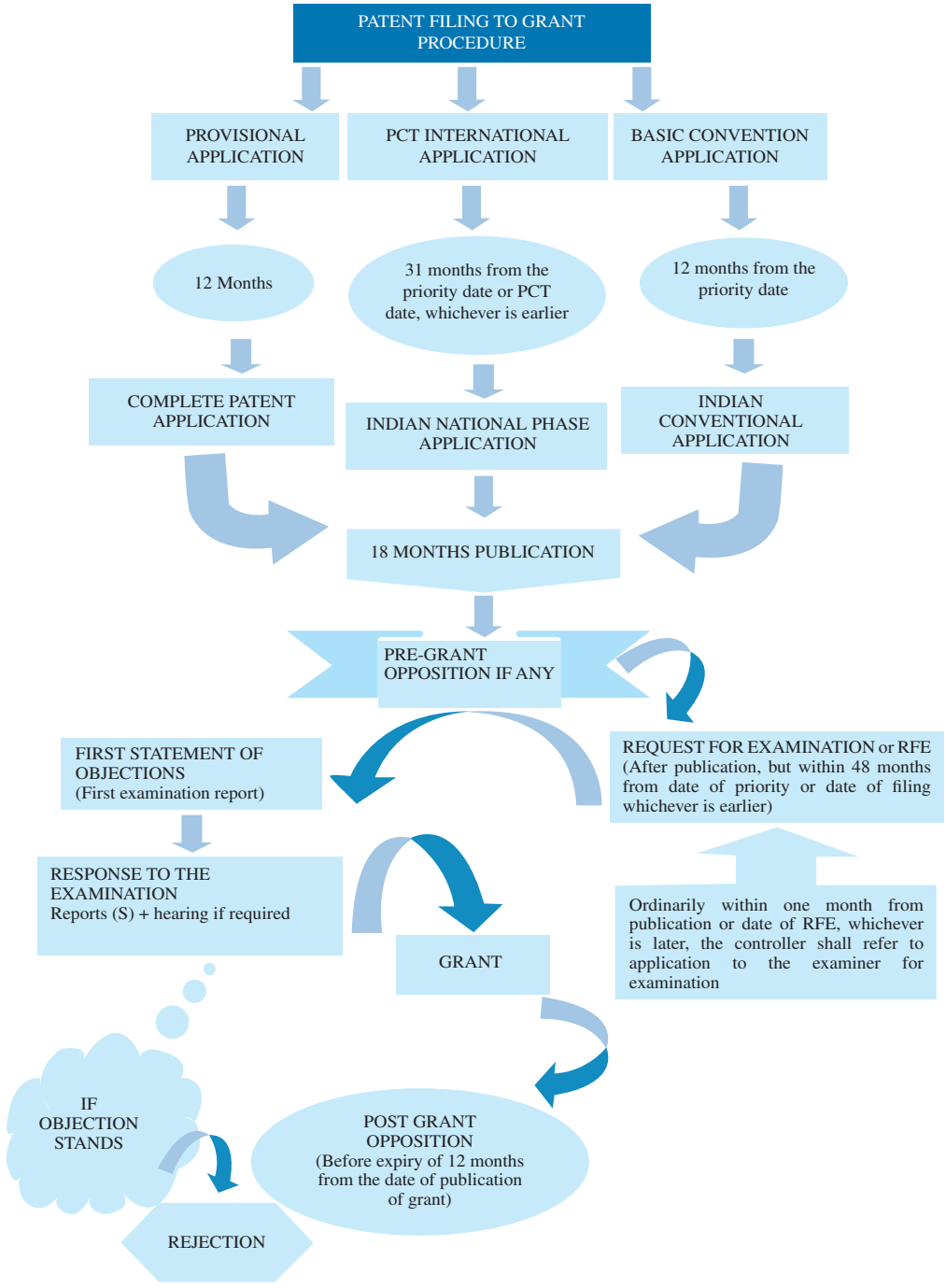
Application for a Patent: An application for a patent can be made by any person claiming to be the true and first inventor of the invention, assignee of the true and first inventor, or legal representative of any deceased person who, immediately prior to death, would have been entitled to make such an application. The application can be accompanied by either a provisional or complete specification.

Examination of the Patent Application: Substantial examination is an essential step in India. A request for examination can be made within 48 months of from the date of priority or from the date of filing of the application.

Opposition to the Grant of Patent: A patent application can be opposed at either pre-grant or post grant of patent. At the pre-grant stage the opposition may be filed by any person within six months from the date of publication of the application or before the grant of patent. Post-grant opposition may only be filed by an interested person after the grant of a patent but before the expiry of a period of one year from the date of publication of the grant of a patent.

Grant of the Patent: After an application for a patent has been found to be in order for grant of the patent, the patent is granted. The details of the grant of a patent are published by the Controller in the official journal so that the patent is open for public inspection. The term of patent protection is 20 years.

Annuities: Annual renewal fees must be paid during the life of an Indian patent. The renewal fee is payable at the expiration of the second year from date of the patent and each succeeding year. Payment must be remitted to The Patent Office before the expiration of the relevant year. The Patent Office will only entertain correspondence about annuity payments from a registered patent agent. Two or more years' renewal fees may be paid in advance if the patentee so desires. A maximum extension of six months may be obtained on payment of the prescribed penalty fees. If the renewal fee in question



Schematic diagram of the patent filing to grant procedure

is not paid within the extended period, the patent will lapse.

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Cadalmin™ Green Mussel extract (Cadalmin™ GMe) contains 100% natural marine bioactive anti-inflammatory ingredients extracted from green mussel Perna viridis. The product is effective to combat chronic joint pain, arthritis/ inflammatory diseases (Indian Patent Appl. No. 5198/CHE/2012). It is an effective green alternative to synthetic non steroidal anti-inflammatory drugs and other products available in the market. Cadalmin™ GMe is an indigenous product, and is highly cost effective with that of the imported products available in the market. Animal model experiments proved the efficiency and safety of this nutraceutical. Cadalmin™ GMe has been commercialized with Accelerated Freeze Drying Company Pvt. Ltd., a FDA, ISO 22000 FSSC 22000:2011 certified flag Ship Company of Amalgam Group of Companies. The commercialization of Cadalmin™ GMe is significant to the mariculture industry and fishermen as this will enhance the demand to produce more green mussels, particularly along the west coast of India.

CHAPTER 4

Potential of CMFRI in Marine Fisheries Sector and Importance with respect to IPR

Open sea green mussel (Perna viridis) farming has been developed during the 1970s by CMFRI and successful dissemination of technology on farming in backwaters on trestles and on-bottom. The farming technology was successfully demonstrated in the coastal waters and estuaries of India with community participation and is now being taken up as a small-scale commercial venture in the various estuaries of Kerala, Tamil Nadu & Maharashtra. Taking Kerala as a model, mussel culture was taken up in other coastal states of India.

CMFRI

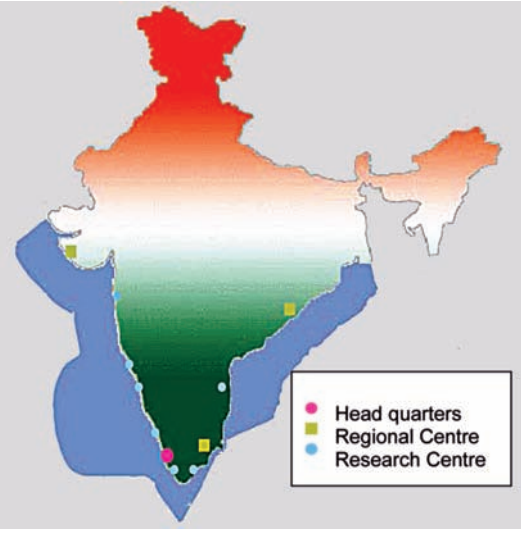
Potential of CMFRI in Marine Fisheries Sector and Importance with respect to IPR

4
CHAPTER

Introduction

The coastline of about 8118 km of Peninsular India with about 20 lakh square km of exclusive economic zone is available for fishing around coastline (Ayyappan *et al*., 2011). High priority is being offered to marine fisheries development with the support for production, marketing, canning the fishes as well as offering suitable training for fishery industry. The fish production has increased compared to other agricultural products (1.1% of the total GDP and 5.3% of the agricultural GDP in India). During 2010-11, the production of marine fishes was estimated to be about 3.07 million tons as compared to a meager 0.534 million tons during 1950-51. Marine fishery registered an annual growth rate of 3.2% with a total fish production of about 3.07 million tons during 2010-11. The total quantities of marine fish and products exported during 2010-11 were recorded to be 813091 tons. The total export was valued as 12901.47 crores during 2010-11 and 10048.53 during 2009-10, an increase of 28.39% over 2009-10. Marine fish has retained its position as the principal export item in quantity terms and the second largest export item in value terms, accounted for a share of about 38.42% in quantity and 20.42% in US$ earnings. An estimated 3.93 million tons of marine fishes are produced from exclusive economic zone around the coastal line. The total quantities marine fish and products exported during 2010-11 was recorded to be 813091 tons as compared to 678436 tons in the previous year (2009-10). Marine fish has retained its position as the principal export item in quantity terms and the second largest export item in value terms, accounted for a share of about 38.42% in quantity and 20.42% in US$ earnings. The harvestable potential of marine fishery resources from Indian EEZ is 3.93 million tones and the potential of inshore waters up to 50 m is 2.28 mt (58%).

Map indicating EEZ and CMFRI RCs



Central Marine Fisheries Research Institute (CMFRI) has grown remarkably in its size, structure and research infrastructure over the years. CMFRI pioneered in the development of marine fisheries and coastal aquaculture industries of the country, and is one of the premier marine research institutes of the world. With the fast changing marine fisheries scenario and emergence of mariculture as an alternate approach for enhancing coastal fish production, the institute has tuned its mandate in consonance with the need of the time. The institute has taken a leading role on frontier areas of research such as stock assessment of marine fisheries, mariculture, marine bioprospecting, high value compounds, biotechnology, development of nutraceuticals and valuable bioactive molecules from sea, natural resource management, Indian fisheries database, statistical or economic tools to assess marine fisheries in India, bioinformatics, remote sensing, and climate change.

A Glimpse of the Technologies Developed by Central Marine Fisheries Research Institute

Technologies in the fisheries can receive protection by patents, trademarks, geographic indications, copyright, and design. These technologies receive protection by one or a combination of different IPRs depending upon the nature of technology (Ravishankar and Archak, 2000). Given the vast and unexplored potential of utilization of aquatic resources, the increasing trend in biotechnological patents in the developed countries, patenting of aquatic genetic resources will have an increasing trend in times to come. The use of aquatic resources has a significant potential in pharmaceuticals, nutraceuticals, high value compounds/ chemicals, cosmetics and food.

For example, technologies have been developed in marine fisheries in India for land-based culture of pearls, fish strains, packages of improved marine finfish and shellfish husbandry practices, natural resource management technologies, improved tools including cage culture technology for open sea fish farming, technologies for making nutraceuticals and value added products, computer software and data sets, and several other processes and products related to fisheries sector, some of which have been safeguarded by patents. CMFRI pioneered in shaping a number of IP protected technologies, which are of direct or indirect benefits to the society and mankind. Design, development and propagation of open sea cage device for cultivating marine fishes along the coastline of India (Indian Patent Appl. No. 31/CHE/2010), cutting edge mariculture technologies of food fishes such as cobia (*Rachycentron canadum*), silver pompano (*Trachinotus blochii*) and *Etroplus* sp are some of the success stories of marine fisheries and CMFRI. The mariculture in open sea cage device will expand a new mariculture space in future. The breakthrough of cobia and pompano breeding is considered as a milestone towards the development of foodfish mariculture in the country. CMFRI achieved the rare feat of joining the elite group of countries (US and Australia) engaged in satellite tracking of yellowfin tuna (*Thunnus albacares*) with pop up satellite tagging of this species in oceanic waters. CMFRI showed the way of land-based culturing of pearl oyster in marine body (Indian Patent Appl. No. 1543/CHE/2009), open sea green mussel and oyster farming, hatchery technology for production of ornamental fish (Indian Patent Appl. No. 3455/DEL/05), edible clams, sea horse, mass scale spat production of green mussel, artemia selective breeding to impart high value traits for use in mariculture (Indian Patent Appl. No. 2063/CHE/2010), biotechnological interventions to control fish diseases and maintain fish health, probiotics,

bioprospecting beneficial microorganisms for aquaculture grade antiboiotic substitute, biocatalysts from beneficial bacterial flora (Indian Patent Appl. No. 203/CHE/2008), gene mining technologies for various important traits, phytoplankton culture and algal biotechnology, production process for sea cucumber *Holothuria scabra* and *Holothuria spinifera* seeds or fingerlings, resource management of the Indian sacred chank, *Xancus pyrum* (=*Turbinella pyrum*) by breeding, nursery rearing and sea ranching, propagation of soft coral *Sinularia kavarattiensis*, fish aggregating devices (FAD), capture based aquaculture of mullets and red snapper, lobster farming in floating sea cages, mud spiny lobsters (*Panulirus polyphagus* fattening in sea cages), image pearl production, cost effective and rapid duplex PCR kit for early detection of white spot syndrome virus of shrimp, Cadalmin™ Varna (Indian Patent Appl. No. 32/CHE/2010) and Cadalmin™ Silo fish feed, which are of direct use of the fish farming communities. Marine organisms too have various potential applications in the area of human health. This has more to do with the relative infancy of marine bioprospecting. In the process of harnessing high value bioactive molecules from marine organisms, CMFRI could able to successfully develop a number of products for use as nutraceuticals for human health. A patent protected product Cadalmin™ Green Mussel extract (Cadalmin™ GMe) containing anti-inflammatory principles from *Perna viridis* to combat joint pain, arthritis/inflammatory diseases developed by CMFRI as an effective green alternative to the synthetic drugs available in the market (Indian Patent Appl. No. 2065-2066/CHE/2010). Cadalmin™ Green Algal extract (Cadalmin™ GAe) is another addition to the pipeline of the nutraceuticals developed by CMFRI (Indian Patent Appl. No. 2064/CHE/2010). Cadalmin™ GAe contains 100% natural and a vegetarian marine bioactive antiinflammatory ingredient extracted from a blend of marine macroalgae with an ecofriendly "green" technology, and is a natural remedy to chronic joint pain and arthritis. The institute has taken a leading role on frontier areas of research such as stock assessment of marine fisheries, mariculture, biotechnology, marine bioprospecting, development of nutraceuticals and valuable bioactive molecules from sea, bioinformatics, remote sensing, and climate change. Most importantly, CMFRI is mandated with natural resource management technologies. Several techniques, protocols, and technologies developed by CMFRI cannot be transferred to the end users. However, these are the vital links to ecosystem, and can be used for human welfare. Some of these natural resource management technologies developed in the area of marine fisheries are trawl ban, fishwatch – spot information system of Indian marine fisheries, national marine fisheries data centre, database on socio- economic evaluation and technology, extension modules, multi-stage stratified random sampling for estimation of marine fish landings in the country and information system, mangrove restoration, conservation of shark and marine mammals, m-KRISHI® fisheries mobile service, documentation of seaweeds, seagrasses, hard corals and shallow water sponges of Indian coastline, among many.

Significant research outputs/ success stories of Central Marine Fisheries Research Institute that are either patent protected/ popularized are detailed under the following heads.

A Device for Breeding and Culturing / Marine Fish in Open Sea (Open sea fish farming in HDPE cage) (Indian Patent Application No. 31/CHE/2010)

Central Marine Fisheries Research Institute is the pioneer to initiate open sea cage culture

for domestic and export oriented open sea marine fish farming in all the Maritime states with the involvement of the fishermen community. The open sea cages are used for cultivating marine fishes, and may be used in domestic and export oriented marine sea farming in cages. The present invention describes a cage culture device for open sea fish farming in High Density Polyethylene Cages (HDPE). CMFRI has developed and experimented with five versions of indigenously fabricated cages at different locations in India. The first three versions were done with 15m diameter high density polyethylene (HDPE) cage. A successful demonstration was carried out with the third version, by involving modifications suggested by marine engineering and naval diving. The successful harvest of sea bass was in April 2008. The fourth version had to be taken into consideration for easy manoeuvring and cost effectiveness of cage in terms of initial capital investment and reduced labour. Thus the size of the cage was optimized at 6 m diameter and demonstrated the culture of finfishes and shellfish at different locations. The latest version is epoxy coated galvanized iron cage (described in the preceding section). Other innovation by CMFRI is the 2 m diameter seed cages for nursery rearing of fry in open waters or ponds and small scale farming of omnivores like pearlspot in Kerala. Based on this, artisanal cages of rectangular frame have been used widely in Byndoor, Karnataka for snappers, pearl spot and mullets. These interventions by cage farming of marine fishes optimally maintain their size and quality. The system is eco-friendly without any human intervention, and a higher survival of above 75% was achieved and sustained. The mariculture in open sea cage devised under the present invention will expand a new mariculture space towards a sustained blue revolution in India, thereby the mariculture scale can be expanded greatly; simultaneously the self-pollution of mariculture can be solved. The open sea cage farming is highly suited for many species like cobia, seabass, mullets, pearlspot, lobsters, redsnappers, seabreams etc in backwater areas and saline creeks apart from open sea.

Open sea cage farming is a promising venture which offers the fishers a chance for optimally utilizing the existing water resources. The open sea cages are used for cultivating marine fishes, and may be used in domestic and export oriented marine sea farming in cages. By integrating the cage culture system into the aquatic ecosystem, the carrying capacity per unit area is optimized because the free flow or current brings in fresh supply of water and removes metabolic wastes and excess feed. Thus economically speaking, cage culture is a low impact farming practice with high economic returns.

National Fisheries Development Board (NFDB) has funded CMFRI, Kochi for demonstration of the open sea cage culture in 14 different locations both in the east and west coast for culture of seabass, lobsters and shrimp. Fishermen, fishermen co-operatives and SHG's involved in the open sea cage culture have shown keen interest to take up this activity as an alternative livelihood. NFDB also proposed to extend 40% subsidy to the entrepreneurs on the capital cost of ₹ 1.30 lakhs not exceeding ₹ 52000/- and 40% on the working capital of ₹ 2.55 lakh not exceeding ₹ 1, 02, 000/-. Therefore the proposed subsidy assistance to take up cage culture would be ₹ 1.54 lakh on the total project cost of ₹ 3.85 lakh for open sea cage culture in 6 meter diameter cage. It is desirable to take up cage culture in clusters for effective management of cage. If the cage culture is taken up by the Department of Fisheries, Fishermen Cooperative Federations/ Corporations then the subsidy could be 90 %.

High density polyethylene (HDPE) cage
(Device for Breeding and Culturing Marine Fish in Open Sea)

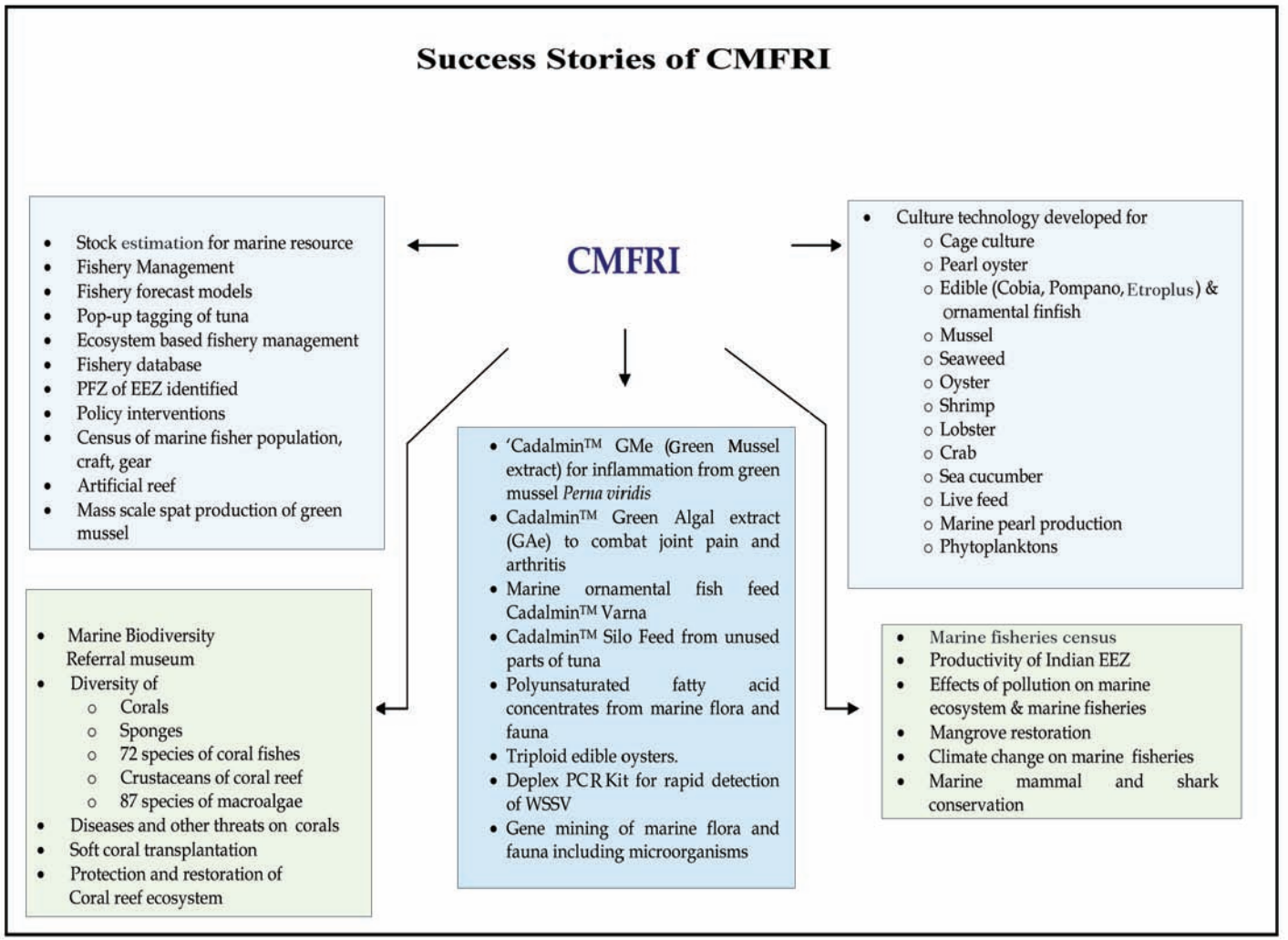
HDPE Cage installation in progress in Kanyakumari coast

HDPE cage with 'silpolin' in the inner bottom net for farming of lobsters

Harvested lobsters from sea cage

Cage cultured Asian Seabass *Lates calcarifer*

Cage cultured Mullet in Pooyyappilly, Kerala


Success Stories of CMFRI
CMFRI
Stock estimation for marine resource
Fishery Management
Fishery forecast models
Pop-up tagging of tuna
Ecosystem based fishery management
Fishery database
PFZ of EEZ identified
Policy interventions
Census of marine fisher population, craft, gear
Artificial reef
Mass scale spat production of green mussel
Culture technology developed for
Cage culture
Pearl oyster
Edible (Cobia, Pompano, Etroplus) & ornamental finfish
Mussel
Seaweed
Oyster
Shrimp
Lobster
Crab
Sea cucumber
Live feed
Marine pearl production
Phytoplanktons
'Cadalmin™ GMe (Green Mussel extract) for inflammation from green mussel Perna viridis
Cadalmin™ Green Algal extract (GAe) to combat joint pain and arthritis
Marine ornamental fish feed Cadalmin™ Varna
Cadalmin™ Silo Feed from unused parts of tuna
Polyunsaturated fatty acid concentrates from marine flora and fauna
Triploid edible oysters.
Deplex PCR Kit for rapid detection of WSSV
Gene mining of marine flora and fauna including microorganisms
Marine Biodiversity Referral museum
Diversity of
Corals
Sponges
72 species of coral fishes
Crustaceans of coral reef
87 species of macroalgae
Diseases and other threats on corals
Soft coral transplantation
Protection and restoration of Coral reef ecosystem
Marine fisheries census
Productivity of Indian EEZ
Effects of pollution on marine ecosystem & marine fisheries
Mangrove restoration
Climate change on marine fisheries
Marine mammal and shark conservation

Epoxy Coated Galvanized Iron (GI) Cage (Indian Patent Appl. No. 5196/CHE/2012)

Epoxy coated galvanized iron (GI) cages are used for cultivating marine fishes, and may be used in domestic and export oriented sea farming in cages. GI cage has a circular shape as this shape makes the most efficient use of materials and better utilization of space. These cages have the diameter of 6 m, height of 120 cm, depth of 6 m, and a total weight of 700 kg. The material used for the construction of cage frame is sturdy galvanized iron pipes of 'B' class quality joined with metallic arc double welding. The galvanized iron pipes used in cage fabrication was 1.5" diameter and 3 mm thickness (B Class), and the structure is provided with single coat epoxy primer and double coat epoxy grey paint to prevent rusting. Additional floatation with fibre barrels of 200 litres filled with 30 Ib air and inflated barrel provides stable platform for operations are included in this system. GI cage worth Rs 1 lakh including netting & mooring and a single crop can recover the investment of input cost. This cage has potential to spread the cage culture technology in the coastal waters of India particularly the protected bay of West Coast. This cage can be used for culturing high value food fish like asian seabass, cobia, pompano, etc.

Epoxy coated galvanized iron cage

Epoxy coated galvanized iron (GI) cage

Broodstock Development, Induced Breeding and Larval Production of Cobia, *Rachycentron canadum*

Cobia (*Rachycentron canadum*) was bred for the first time in India at CMFRI during February, 2010. Their Fl generations have reached a size of 10-15 kg at Mandapam and Karwar. The Fl generation has also reached maturation state both in male and female. One of the males spawned and fertilized the eggs of females collected from wild at CMFRI, Mandapam. The technology has been disseminated to the fish farmers in East Godavari districts of Andhra Pradesh, and presently being demonstrated to several needy farmers on demonstration basis. This path-breaking technology will benefit the fishermen and will contribute towards the blue revolution of India.

Cobia (*Rachycentron canadum*) bred for the first time in India at CMFRI

Cobia fingerlings

Cobia sub adults

Cobia brooder

Breeding of Silver Pompano, *Trachynotus blochii*

Among the many high value marine tropical finfish that could be farmed in India, the silver pompano, *Trachynotus blochii* is one of the topmost, mainly due to its fast growth rate and high market demand. It is well understood that for commercialization of aquaculture of any species, the vital requirement is the availability of technology for seed production and farming. Even though the seed production technology and the potential of farming of Florida Pompano (*T. carolinus*) has been well established in the late 1990s, India is a late beginner in the aquaculture research of pompano. Central Marine Fisheries Research Institute initiated aquaculture research on pompano from 2008 and the first successful broodstock development, induced breeding and larval production is now successfully accomplished. It can be considered as a milestone towards the development of pompano aquaculture in the country. Silver pompano is caught only sporadically in the commercial fishery and hence its natural availability in the sea is rather scarce. It is a much sought after species and hence the demand can be met only through aquaculture.

The farming of pompano can be successfully carried out in ponds, tanks and floating sea cages. The species is able to acclimatize and grow well even at a lower salinity of about 10 ppt, and hence it is suited for farming in the vast low saline and brackishwaters of our country besides its potential for sea cage farming. Karnataka Fisheries Development Corporation has taken up the marketing in Bangalore, where it is popularly referred as American Pomfret. By separating the nursery phase it is possible to have two harvests in one year. About 12,000 seed can be stocked in one hectare and about 5 tons of fish can be harvested for each crop. Silver pompano looks and tastes like silver pomfrets and fetches a farm gate price of about Rs 200/kg. Such fish are in great demand in all Metros, particularly during April-July period due to the national trawl ban on east coast and west coast successively. The demand during this period is estimated at about 2 lakh tonnes and fetches the highest price during this period. In this context silver pompano's harvest gains lot of importance to aquaculture along with other marine fish already bred by CMFRI to bring lakhs of acres of barren coastal saline low lying lands to produce the high valued fish, thus improving the food production and nutritional enhancement of the country.

The present success in the pompano breeding at CMFRI is a major step in the development of seed production technology. Pompano is a potential mariculture giant, which has vast domestic and global business prospects. After the successful larval rearing they were transported by road from Mandapam, near Rameswaram in Tamilnadu to Antervedi in the East Godavari District of Andhra Pradesh at a distance of 1200 km and stocked in 1 acre pond of a farmer. About 3,600 seed were stocked and fed with indigenous pellet feed and maintained good pond environment, resulting in a survival of more than 95%. During the course of 8 months they reached a size range of 450-550 g weight, which is an excellent table size for marketing. The harvest was conducted on l7th April, 2012 in presence of leading aqua farmers of coastal districts of AP, local MP and peoples representatives, press and electronic media.

Harvest of Silver Pompano in progress
at Antervedi of East Godavari district of Andhra Pradesh

A Method and Composition for Land-Based Culturing of Pearl Oyster in a Marine Body (Indian Patent Application No. 1543/ CHE/2009)

The pearl oysters are used for ornamental purpose, and may be used in domestic and export oriented business. CMFRI showed the way of land-based culturing of pearl oyster in marine body, which is of direct use of the fish farming communities. The land-based tanks are provided with filtered seawater through a slow sand filtration device, wherein the seawater was supplemented with mixed phytoplankton as feed for pearl oysters, wherein the oysters are attached to stones. The present invention (1543/ CHE/ 2009) also optimized the nacre production and coating over the nucleus in uniform thickness, while optimally maintaining the color and quality.

Land-based cultured pearl oyster

Pearls obtained from land-based cultured pearl oyster

This invention further describes an optimized protocol to harvest 3-5 mm pearls in about 6 months from the date of implantation. The system is eco-friendly without any human intervention, and a higher survival of about 85-95% from spat to implantation size was achieved and sustained. The land-based pearl oyster farming process and device mentioned in the present invention facilitate cultivation of good quality oyster pearl under marine ambience, clean and hygienic environment with least risks from microorganisms, toxic gases, foulers and borers, natural calamities and additional advantage of high yield and attractive return.

Anti-inflammatory Principles from Green Mussel *Perna viridis* L. to Combat Joint Pain and Arthritis

- A process to concentrate anti-inflammatory principles from green mussel *Perna viridis* L. and a product incorporating these ingredients (Indian Patent Application No. 2065/CHE/2010).
- A product containing anti-inflammatory principles from green mussel *Perna viridis* L. and a process thereof (Indian Patent Application No. 2066/CHE/2010; 5198/CHE/2012).

Cadalmin™ Green Mussel extract (Cadalmin™ GMe) contains 100% natural marine bioactive anti-inflammatory ingredients extracted from green mussel *Perna viridis*. The product is effective to combat chronic joint pain, arthritis/inflammatory diseases. It is an effective green alternative to synthetic non steroidal anti-inflammatory drugs (*viz.*, aspirin/containing drugs having undesirable side effects) and other products available in the market. Consuming Cadalmin™ GMe will avoid unfortunate side effect of these synthetic non steroidal anti- inflammatory drugs. The active principles in Cadalmin™ GMe isolated from *P. viridis* were competitively inhibit inflammatory COXI, II and LOXV in an inflammation and oxidative stress reaction, resulting in decreased production of inflammatory prostaglandins and leukotrienes, and its activity was found to be superior to the synthetic non steroidal anti-inflammatory drugs available in the market. It was found that the active principles isolated from *P. viridis* and concentrated in the product registered higher inflammatory COXII and LOXV inhibition (70-75%) than aspirin and indomethacin (55-66%, 5mg/ml). *In vivo* animal model studies revealed that the active principles effectively suppressed (64 - 77%, 2-4h) the edema produced by the histamine, which indicates that they exhibit its anti-inflammatory action by means of either inhibiting the synthesis, release or action of anti-inflammatory mediators. Cadalmin™ GMe is designed to find a unique way to prevent the degradation by air, moisture, heat and light and to maximize the activity. The product is free from deleterious carcinogenic *trans* fatty acids, free radicals/free radical adducts, low molecular weight carbonyl compounds, and has been proved to be safe from a long term acute and chronic toxicity studies on experimental subjects. This product is available as capsules and packaged in food grade polypropylene bottles. Cadalmin™ GMe is an indigenous product, and is highly cost effective with that of the imported products available in the market.

Cadalmin™ GMe has been commercialized with Accelerated Freeze Drying Company Pvt. Ltd., a FDA, ISO 22000 FSSC 22000:2011 certified flag Ship Company of Amalgam

Cadalmin™ Green Mussel extract
for use against arthritis

Group of Companies. The commercialization of Cadalmin™ GMe is significant to the mariculture industry and fishermen as this will enhance the demand to produce more green mussels, particularly along the west coast of India.

An Anti-Arthritic Vegetarian and 100% Nutraceutical Cadalmin™ Green Algal extract (Cadalmin™ GAe) from Seaweeds or Marine Macroalgae (Indian Patent Application No. 2064/CHE/2010; 5199/CHE/2012)

Cadalmin™ Green Algal extract (Cadalmin™ GAe) provides a unique blend of 100% natural bioactive anti-inflammatory ingredients extracted from seaweeds by an ecofriendly "green" technology to combat inflammatory pain and arthritis. Many of the allopathic prescriptions include Non Steroidal Anti-Inflammatory Drugs and cyclooxygenase inhibitors used in controlling arthritic conditions have known side effects, especially with long term usage. The side-effects of synthetic drugs led the scientists of CMFRI to investigate into natural products for safer and effective alternatives. Seaweeds, which are natural bounty of sea, were found to possess valuable compounds that can offer relief to arthritis and associated joint pain. An intensive research in this area led them to perfect a patented anti-arthritic and 100% vegetarian nutraceutical Cadalmin™ GAe from these valuable resources. The active principles in Cadalmin™ GAe competitively inhibit pro-inflammatory cyclooxygenase-II and lipooxygenase enzymes, resulting in decreased production of inflammatory prostaglandins and leukotrienes, and its activity was found to be superior to the synthetic non steroidal anti-inflammatory drugs available in the market. The efficiency of Cadalmin™ GAe to inhibit these inflammatory enzymes stands at 64-94% as compared to 40-52% for the popular painkiller. Time dependent *in vivo* animal model studies on experimental subjects revealed the superior inhibition of inflammatory response to the tune of 73-76 % by Cadalmin™ GAe. The active ingredients in Cadalmin™ GAe also suppress the build-up of uric acid in hyperuricemic patients.

Cadalmin™ GAe is a pure natural and 100% vegetarian product, with its therapeutic values, is an import substitute with an international appeal, providing great market potential especially for the large vegetarian population in India and abroad. The unique biochemical engineering techniques adopted to retain the anti-inflammatory activities in the preparation of Cadalmin™ GAe assures higher shelf life. The product has been proved to be safe from the acute and chronic toxicity studies on experimental subjects. The hygienically processed active ingredients are housed in low moisture content 100% cellulose based Naturecaps capsules that meet the dietary or cultural needs of customers that follow a vegetarian lifestyle. This is the first product developed by an ICAR institute from seaweeds for use against arthritis and joint pain.

Formulated Feed for Marine Ornamental Fishes (Indian Patent Application No. 32/ CHE/2010)

Marine ornamental feeds are used in the aquariculture of marine ornamental fishes, which include maintenance, breeding, larval rearing, and aquarium keeping. This invention describes an optimized method to produce feed for marine ornamental fishes. Presently, formulated feed for marine ornamentals is not indigenously produced, and the demand is met through imports with a price tag in the range of Rs. 4000 a kg. CMFRI has developed and launched a sequel of dry formulated feeds named Cadalmin™ Varna as an import substitute. Varna is a scientifically evaluated slow sinking marine ornamental fish feed containing, 38% protein, 9% fat, 39% carbohydrates, 7%

Cadalmin™ Green Algal extract

Ornamantal fish feed Cadalmin™ Varna

ash (minerals) and less than 2% fiber. The slow sinking crubles are available in three particle sizes 0.25 mm, 0.75 mm, and 1 mm produced through twin screw extrusion technology, which is the stat of art in aquatic feed production. These feeds are sold in 50 g pouches and containers i.e., ₹ 400 a kg.

A Phytase Produced Extracellularly from Thermophilic Bacterium (Indian Patent Application No. 203/CHE/2008)

A strain of a thermophilic bacterium *Bacillus licheniformis* MTCC 6824 was isolated from the mangrove ecosystem of Kerala and the said bacterium was found to produce an extracellular phytase in specific culture media. The phytase has low Michaelis constant (K_M) for phytic acid, and decompose phytic acid, an anti-nutritional factor contained in many plant feed ingredients, thereby improving the nutritive value of feed and efficient utilization of phosphate released during phytic acid breakdown. The phytase of the present invention can be used in monogastric animals like fish and poultry and also shrimps, prawns and crabs. This is the first report of isolating and purifying phytase from *Bacillus licheniformis* isolated from mangrove ecosystem of Kerala.

Soil sediment of Mangalavanam mangrove ecosystem used to isolate *Bacillus licheniformis* MTCC 6824 (as inset)

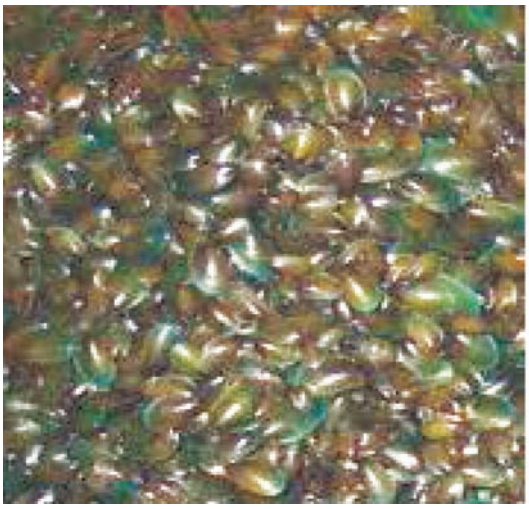
Fish Feed (Cadalmin™ Silo Feed) from Unused Parts of Tuna

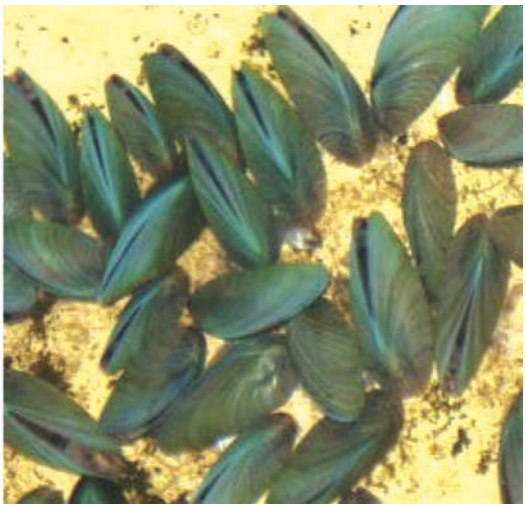
The head, intestine, and unused parts of tuna are made into silage and the other ingredients like rice bran and oil cakes have been supplemented with the tuna waste by extrusion technology. The feed has been tested on Asian seabass, ornamental fish, coldwater fish (trout), shrimp, and lobster. This feed may be an import substitute with high protein content (35%) and low cost (₹ 25/- per kg). Protein content has been improved upto 35% by supplementing with soyabean protein. It is also a process to utilize the tuna waste, which otherwise are buried by fishermen in beach, thereby polluting the adjacent lagoon. Rational utilization of tuna waste will be additionally helpful to prevent environmental pollution. Fish farmers, one seafood exporter in Tuticorin, and feed processing industries have expressed interest in the feed developed from unused parts of tuna. The imported feed cost about ₹ 85/- per kg. However Cadalmin™ Silo Feed is about ₹ 25/- per kg, and, therefore, has market potential. This technology has been developed in collaboration with Central Institute of Fisheries Technology, Cochin.

Mass Scale Spat Production of Green Mussel *(Perna viridis)* in Visakhapatnam Hatchery

Green mussel *(Perna viridis)* has been spawned and larvae reared successfully to settlement of spat at the Visakhapatnam hatchery of the Visakhapatnam Regional Centre of CMFRI. The spats have been successfully settled in the hatchery. The 'D' stage larvae were obtained within 20-24 h. The Umbo stage was reached on the 8th day and the eyespot stage reached on the 16th day before being reached the Pediveliger stage on the 19th day. Spat settlement began on the 21st day and continued up to the 30th day. Over 2.0 lakh spat have been successfully settled in the hatchery. The technology can be further refined for transfer to end users. Green mussel spat production technology is suitable for enclosed bays, coastal areas and estuaries. It is an alternative source of mussel seed for the mussel farming sector, which is presently dependant on the wild for seed. Assured supply of mussel seed will promote farming and enhance green

Cadalmin™ Silo Feed from Unused Parts of Tuna



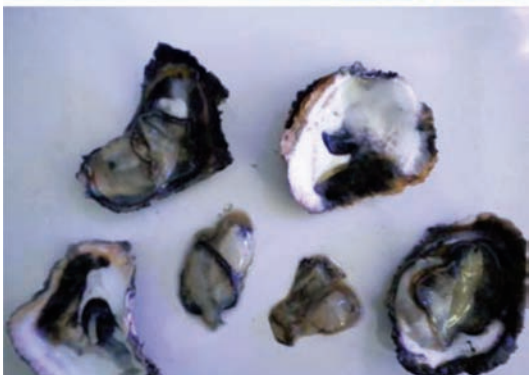


Mass scale spat production of green mussel (*Perna viridis*)

mussel production and increase aquaculture production.

Oyster Culture Techniques

Edible oyster farming technology developed and commercialized in the coastal fishing villages of Kerala. The oyster farming methods are broadly divided into (i) on-bottom and (ii) off-bottom culture. In the on-bottom culture, the seed oysters are sown on the ground. This method is substrata-specific and the area should be free from silting and predators. When oysters are grown by off-bottom methods, the advantages lie in better growth and good condition of the meat. The methods involved in off-bottom culture are (1) rack & tray, (2) rack & string, (3) stake and (4) raft. In the raft method oysters are suspended from floating rafts. Rafts are constructed using bamboo or wooden poles and are floated with empty oil drums or wooden barrels. Once raft is positioned by anchors, shell strings with attached oyster spat are hung from the raft for further growth. The average productivity has been



Oyster Culture rafts and edible oyster *Crassostrea madrasensis*

estimated as 70 kg shell-on oyster per square meter.

Mussel Farming Technology

Open sea green mussel *(Perna viridis)* farming has been developed during the 1970s by CMFRI. The farming technology was successfully demonstrated in the coastal waters and estuaries of India with community participation and is now being taken up as a small-scale commercial venture in the various estuaries of Kerala, Tamil Nadu and Maharashtra. The raft mussel culture is similar to long line culture in that the mussels are suspended on droppers but these are suspended from the raft instead of the long lines. The raft itself is anchored to the seabed removing the need for several anchoring systems. Long line culture however, creates less of a visual impact, and the droppers can be spaced further apart to maximize the use of the available phytoplankton. Fixed suspended culture for mussel farming developed by CMFRI is the simplest of the rope-web method used for green mussel cultivation in India. The main purpose of the pole is to support the structure. In between these poles, ropes are suspended either vertically or kept horizontally where the depth is a limitation.

Mussel farming practice was adopted by 13 shrimp farmers during 2009-2010 as a group farming activity in Kodi Kanyan, Udupi. MPEDA, Karwar extended financial support to four mussel-farming groups. Six racks were fabricated at 1.5-2.5 m depth (during low tide) in Sita estuary by 13 fishermen. Coir ropes of 0.75-2.5 m length were seeded in batches with *Perna viridis* at the rate of 750-1500 g/m. Seeding was carried out in two phases. Initially the seeding was carried out from last week of October to the first week of November 2009. Mussel seeds ranging from 46 to 50 mm in size at seeding attained 90 mm in five months, with a monthly growth rate of 8.4 mm. The mussels were harvested from five racks and marketed shell-on. The produce realized a farm gate value of Rs. 1.15 – 1.25/ shell-on without depuration.

Mussel rack at Kodikanyana

Production Process for Sea Cucumber *Holothuria scabra* and *Holothuria spinifera* seeds or fingerlings

Production of Sea Cucumber *Holothuria scabra* and *Holothuria spinifera* fingerlings are suitable for the east coast of India. In view of the over exploitation of sea cucumber *Holothuria* spp from natural bed in the Gulf of Mannar, Pak Bay and Lakshadweep, MOEF, Govt. of India has restricted the collection of brooders from natural beds. Sea cucumber is at present included under the Schedule of the Indian Wildlife Protection Act, and hence commercialization of sea cucumber can't be taken up. Seed production of holothurians with respect to feeding regime, suitable microalgae, environmental conditions and stocking densities for hatching larval and juvenile rearing have been standardized by CMFRI. The seed production is standardized and 11335 numbers of juvenile *H. scabra* having a mean size 23 mm, produced during various spawning trials were sea ranched around Van Island and Tuticorin. The technology will be helpful in increasing the production of export quality bech-de-mer (by product of sea cucumber) from Indian subcontinent. The technique of seed production and subsequent sea ranching would be beneficial to lift the ban on sea cucumber trade, which will pave a way for the social up-liftment of poor coastal villagers.

Pearlspot *Etroplus suratensis* Seed Production and Culture Technology

The species which is the State Fish of Kerala is in high demand in the region. The current production is only 200t and the demand cannot meet the supply. Lack of continuous supply of seed is the major constraint for this. CMFRI has developed a farmer friendly, low input and cost-effective technology for seed production of the species with maximum survival of larvae. Cage culture of *E. suratensis* has also been standardized. Cages of size ranging from 2- 4 m is found ideal for the culture of *E. suratensis* in backwaters. An average weight of 200 g/fish can be obtained in cages using indigenous low cost feed in 6-8 months of culture with a survival of 70%. The seed production technology has been

H. scabra *H. spinifera*

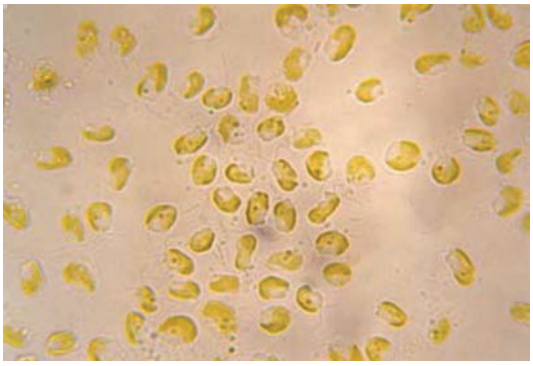
Hatchery produced sea cucumber juveniles (two months old)

transferred to local farmers and cage culture has been demonstrated to local farmers and SHGs. The seed raised by CMFRI technology is competent with the wild seed collected from Cochin backwaters in quality and yield. The cage culture of *E. suratensis* is considered better than pond culture in terms of growth and production.

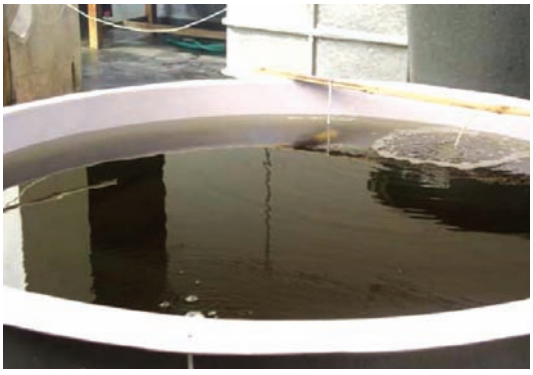
Etroplus suratensis seed production and culture technology

Phytoplankton Culture Technology

Phytoplankton culture technology has been developed by CMFRI for marine micro algae and a few fresh water microalgae; major species in stock culture are *Chaetoceros calcitrans*, *Isochrysis galbana*, *Dunaliella salina*, *Nannochloropsis* sp, *Chlorella salina*, *Dicrateria*, and *Tetrasemis* sp. These are cultured for giving as food of various larval stages of marine organisms. These marine microalgae are used as larval feed in many industrial hatcheries. Phytoplankton culture technology developed by CMFRI can be used for many industrial purposes through different biotechnological applications. This culture technique is environmental friendly and conforms to the regulatory norms.



Isochrysis galbana



Phytoplankton culture facility in CMFRI: Algal mass culture (*Chaetoceros* sp)

Capture Based Aquaculture (CBA)

Through capture based aquaculture system the juveniles of wild fishes caught are reared to marketable sizes in captivity. Estuarine and coastal waters of Karnataka is known for the abundance of finfish seeds of *Lutjanus* spp, *Genes* spp, *Etroplus* spp that are caught in the seines, casmets and gillnets operated along the coast. Usually these juveniles are

discarded or are sold at a low price. An attempt was made to popularize the concept of capture based aquaculture by judiciously utilizing these seed resources. The fishermen society 'Sampradayaka Meenugara Sangha, Byndoor Valaya' of Upunda village located at Byndoor participated with the researchers from CMFRI, Mangalore. The concept of CBA was introduced in this village by collection of *Lutjanus argentimaculatus, Etroplus suratensis* and *Lates calcarifer* fingerlings and stocking in floating cages of 2.5 m x 2.5 m x 2 m, made of netlon (mesh of 30 mm) lined with nylon net. The netlon cages was designed and fabricated by CMFRI with the participation of local fishermen. Feeding was done with locally available trash fish and also fish waste from fish processing areas/plants. The *Lutjanus* sp attained an average weight of 755 ± 415g ranging from 105 to 1,914g. The

Farmed red snapper *Lutjanus argentimaculatus* in Mangalore

pearlspot ranged from 37-222 g. The total production from the cages including seabass, red snapper and pearlspot was around ~400 kg realizing a farm gateprice of ~Rs 75, 000 per cage.

The fishermen view this as an alternative source of fish when adverse climatic conditions prevent them from venturing into the sea. This concept has been popularized along the coast of Karnataka. Demonstration of this methodology encouraged the fishermen to install cages of similar type in the estuary and at present many cages stocked with fingerlings of *L. argentimaculatus*, *E. suratensis* and *L. calcarifer* are found in the village. This concept of CBA was adopted by the fishermen and the diffusion of the technology in this village has been phenomenal. The popularization and adoption of the concept of CBA by the fishermen would generate alternate livelihood, income and contribute to fish production of the region.

***In vitro* formation of nacreous layer on a shell bead with respect to pearl and abalone (Patent Application No. PCT/ IB2006/003299)**

The patent has been applied for the basic technology developed for *in vitro* formation of nacreous layer on a shell bead with respect to pearl oyster and abalone. *In vitro* secretion of crystals and formation of nacreous layer on a shell bead have been achieved through mantle tissue culture of the pearl oyster *Pinctada fucata* and the abalone *Haliotis varia.* The study was also aimed at developing appropriate media for the mantle explant culture of abalone *Haliotis varia*. The effect of different media *viz.*, L-15, Ham's F12, M199 was studied in combination with 10% Fetal Calf Serum (PCS) and 10% tissue extracts of gonad, mantle and whole body of abalone, *H. varia* to understand cell behaviour, cell yield and cell adherence in mantle explant culture of *H. varia*. Addition of whole body extract facilitated in cell adherence followed by the addition of mantle extract. Further study revealed continuous growth of nacre *in-vitro* up to 14 months.

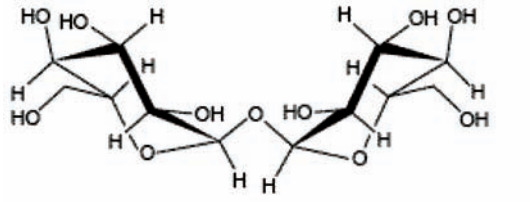
Hatchery Technology for Production of Damselfish (Indian Patent Application No. 1638/DEL/2004)

Most of the marine ornamental fishes traded are coral reef fishes collected from wild. This results in damaging the fragile corals and over harvesting of the species in demand. Among the most commercially traded families of reef fishes, family Pomacentridae dominates, accounting for nearly 43% of all fish traded. Methodologies for breeding and seed production of damselfishes were developed and standardized in CMFRI. The methodologies can be scaled up to commercial level production.

Hatchery Technology for Production of Damselfish

A Process to Prepare Naturalised *Artemia francesciana* from Indian Subcontinent with High Docosahexaenoic Acid and Trehalose for Aquaculture Applications (Indian Patent Application No. 2063/ CHE/2010)

The object of this invention is to prepare naturalized *Artemia*, a live feed with docosahexaenoic acid and trehalose as a quality index for use in larviculture. A process to prepare docosahexaenoic acid, essential polyunsaturated fatty acid rich *Artemia* nauplii in a time course enrichment using different marine sources was delivered. In another embodiment, a process to prepare *Artemia* with high trehalose, protein and carotenoid contents in a specific salinity has been delivered. This invention will lead to large scale production of trehalose in commercial level as an alternative to the natural source.



Structure of naturally occurring isomer of trehalose, α, α, 1, 1-D- glycopyranosyl-D-glucopyranoside

Naturalized *Artemia francesciana* from Indian subcontinent with high docosahexaenoic acid and trehalose

Polyunsaturated Fatty Acid (PUFA) Enriched Formulation

Long-chain polyunsaturated fatty acids (LC-PUFAs), *viz.*, eicosapentaenoic acid (EPA, 20:5*n*-3), and docosahexaenoic acid (DHA, 22:6*n*-3) are widely available in a large variety of marine organisms. These LC-PUFAs are recognised to have special pharmacological and physiological effects on human/animal health. These LC-PUFAs are essential fatty acids in the diet of animals and human beings, because they cannot synthesize it *de novo* from precursor molecules. Therefore they require greater concentrations of PUFAs for their growth, reproduction and survival. Marine fish oils are preferentially used as raw material to prepare PUFA concentrates. Methods to develop polyunsaturated fatty acid concentrates from marine sources by chemical and lipase-catalyzed procedure

Eicosapentaenoic acid

Sardine oil used raw material to prepare PUFA concentrate

Eicosapentaenoic acid enriched polyunsaturated fatty acid concentrate developed by CMFRI

were optimized for use as a source for enriching larval feeds and broodstock diets of marine finfish and crustaceans and as nutraceutical supplements. In this process marine fish oil was enriched through chemical, biochemical and microbiological procedures to formulate EPA-rich emulsion.

Fish Aggregating Devices (FAD) - Cement & Concrete Moulded Modules for Laying of Artificial Reefs (Indian Patent Appl. No. 5197/CHE/2012)

Cement & Concrete Artificial Reef modules developed by CMFRI include grouper module, well ring module, and reef fish module. These modules are hardy and can withstand strong ocean currents. They settle easily and floral growth on the surface with associated fauna takes place within 4-6 months. Fish aggregations improve towards the end of the maturation phase. With aggregation of fishes and other biota in and around the artificial reefs, increased availability of fishes will add to the income of artisanal fishermen particularly those involved in coastal fishing using hooks and lines. Further, there will be a considerable reduction in scouting time, which save time and fuel costs.

Grouper module

Reef fish module

Artificial reefs contribute to a very great extent for enhancement of various biological resources and thereby increase in fish production also. Installation of artificial reefs in the selected coastal districts will increase fish population in the inshore waters and it will continue to increase fish catches in the years after installation. This will lead to an increase in the income of the artisanal fishermen, particularly during the lean seasons. This technology has been offered to Tamil Nadu Fisheries Department on Consultancy mode.

Image Pearl Production

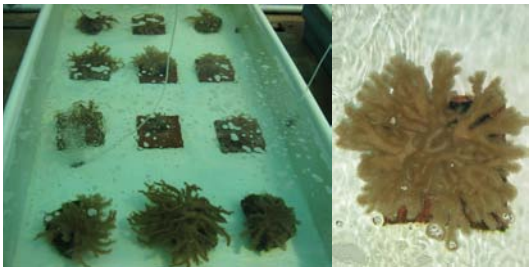
The principle behind the technology is to utilise of ability of the pearl oyster to coat any foreign object implanted in the shell cavity with nacre (layers of pearl). Any idol moulds or half pearl nuclei implanted can be coated with pearly layer resulting in a natural pearl called image pearl. Pearl oyster is farmed in the sea in cages and implanted with nuclei to produce image-pearls. The technique is eco-friendly, no harmful chemicals are used or increase in CO_2 emission. Each image can be sold for a price ranging from ₹ 500 to 5000 depending on the quality, size, colour etc. resulting in better profits than spherical pearls. Cost of

production of nuclei used for implantation is cheaper than spherical nuclei, which are imported at present. This technology will improve the social and economic status of weaker section of the society like fishermen, gold smiths and will develop allied small scale industries like pearl nuclei production units, pearl extraction and processing units.

Image pearl

Propagation of Soft Coral *Sinularia kavarattiensis*

Soft corals are known to possess valuable compounds, which are useful in the development of drugs and are valuable sources for use in pharmaceuticals. However, continuous exploitation from the wild may lead to depletion of their stock. Hence, development of propagation techniques for important soft corals is imperative for mass-scale production. In the process of the development of this technology of propagation of soft coral *Sinularia kavarattiensis*, the parent stock was successfully domesticated in the laboratory conditions. About 25 well established colonies were grown in the sea by suspending in small plastic cages which showed extremely good growth and survival. Of the many substrata tried, tiles and concrete blocks were found to be ideal for quick attachment and growth. The time taken for attachment to the substratum is about 2 to 3 weeks. The fully established soft coral colonies are tied to plastic cages and suspended in the coastal waters at Mandapam for assessing their survival and growth. Indoor propagation and large-scale production of soft coral colonies can fetch very high revenue.



Parent colonies of soft coral

Hatchery Technology for Edible Clams

CMFRI developed the technology for hatchery production of seeds of edible clams *Paphia malabarica* and *Meretrix meretrix*. The brood animals were collected and conditioned under laboratory conditions and thermally stimulated. The fertilized eggs were collected and reared under hatchery conditions with microalgal feed. Baby clams were nursery reared and used for relaying in 'intertidal pen' and production of adult clams. The hatchery produced and nursery reared clams of less 5 mm reached adult size of 35-40mm/14g within a period of 10-12 months. The average production of shell on clams obtained in intertidal pen culture system ranged from 7.2-9.2 tons/ha/year at an average recovery of 20% of the seeded clams. The technology can be adopted as an alternate/additional income generation for farmers.

Hatchery Technology for Edible Clams

Breeding, Nursery Rearing and Sea ranching of the Indian Sacred Chank, *Xancus pyrum* (=*Turbinella pyrum*)

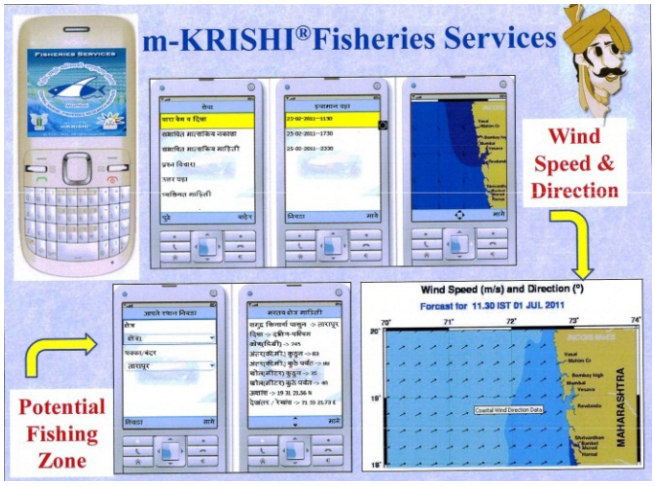
Sacred chanks collected from various chank bed areas of Gulf of Mannar indicated two distinguishable sub-species *Xancus pyrum* var. acuta, *Xancus pyrum* var. obtuse, *Xancus pyrum* var. comorinensis and *Xancus pyrum* var. irupiravi. The captive rearing and culture of live chanks were perfected. Brood stock, egg capsules and baby chanks of specific age groups could be maintained through a well defined seawater flow-through system with a water exchange rate varying from 1 to 1.5 lit /min. Based on their breeding behavior, males and females could be specifically and individually marked and reared in the brood stock tanks. After their mating, the females started releasing the egg capsules that take a few hours to almost 3 days. The total number of chambers in each capsule varied between 20 and 33 per capsule. Depending on the hydrological conditions of the water and after 30 to 35 days of release of egg capsules, babies hatched out from the egg capsules. The juveniles of *Xancus pyrum* rasp the wall of egg chamber with their radula before being came out from their respective chamber. The sacred chank is a non-migratory species, which lives in restricted chank beds. Through the present technology generated, it is possible to breed them in laboratory conditions, grow the babies to the suitable size for sea ranching.

Sacred chank (Jadhi variety)

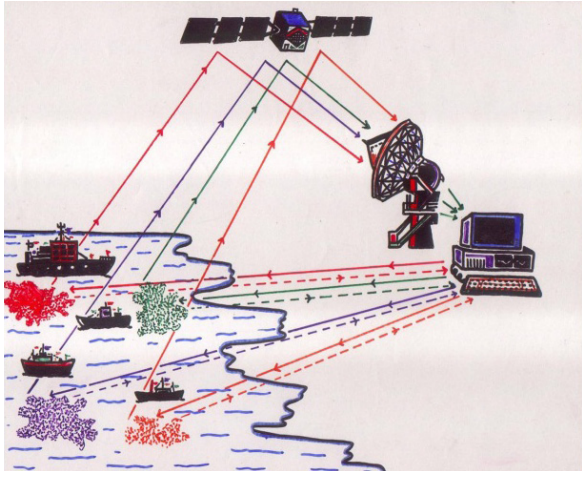
Sacred chank (Patti variety)

m-KRISHI Fisheries Mobile Service

The 'm-KRISHI® Fisheries Mobile Service' is backed up by collating, analysing and integrating thermal, wind speed and algal movement data, and packaged in a readily usable/ understandable mapping format to the fisher communities. This service, being mobile based, ensures continuity and dependability in reaching the communities most effectively and quickly as compared to other sources of dissemination tried in the past even during the periods of frequent power failures in the area. This technology has been transferred to Tata Consultancy Services Innovation laboratory. Sixteen mobile handsets have been distributed to identify beneficiaries who can relay information to the community in selected villages. It is estimated that by using the service at 5% level, currently the fishers are able to save 5 lakh liters of diesel per year costing around ₹ 250 lakhs and the Maharashtra State Government is likely to save an amount of ₹ 52.35 lakh/year on subsidizing this diesel.



'm-KRISHI®-Fisheries mobile service' showing PFZ and wind advisories



Diagrammatic representation of PFZ advisory generation, processing and display

Hatchery Technology for Production of Clown Fish (Indian Patent Application No. 3455/DEL/05)

Marine ornamental seed production is a lucrative business, and an environmentally sound alternative to harvesting them from their reef habitat. Among the different marine ornamental fishes, the genera *Amphiprion* and *Premnas* belonging to the family Pomacentridae and sub family Amphiprioninae commonly known as "clown fishes or sea anemone fishes". The fishes and anemones were fed two times per day with wet feeds such as meat of shrimp, mussel and clam at the rate of 15% of their

Marine Ornamental fishes

body weight and enriched live feeds like *Brachionus plicatilis*, artemia nauplii and adult artemia. The hatchling emerged on 8th day of incubationand and completed their larval phase in about 15 days.

Resource Management of Endangered Indian Sea Horse *Hippocampus* sp by Breeding, Nursery Rearing and Sea Ranching

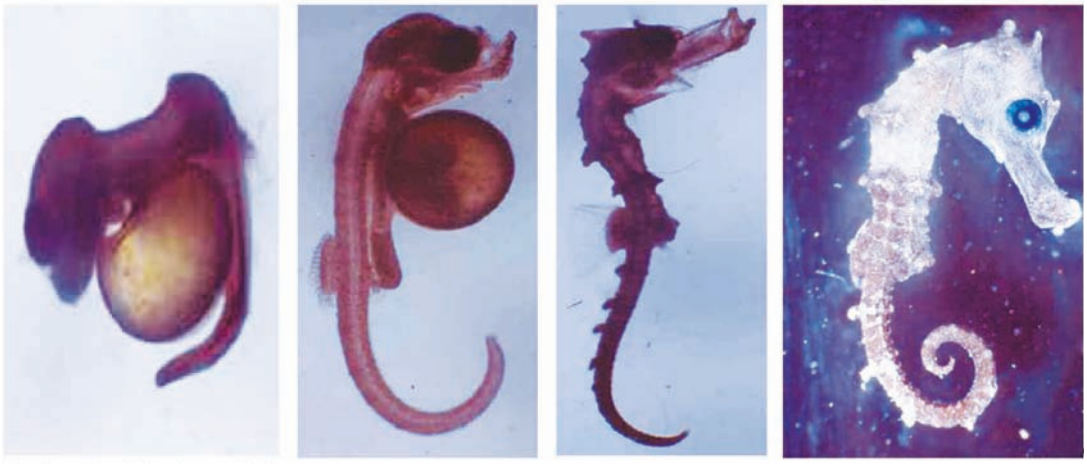
Seahorses are sought in great numbers, for use in traditional medicines, as aquarium fishes and as curios. All the seahorses belong to one genus, *Hippocamus*. Seahorses are listed as vulnerable in the IUCN Red List of Threatened Animals. Status of exploitation, species, size of seahorses and information on trade of dried seahorses along the Palk Bay coast of Tamil Nadu were accomplished by CMFRI. CMFRI also developed suitable captive rearing system to maintain the adult *Hippocampus kuda* and *H. trimaculatus.* Survival of baby seahorses in hatchery condition was enhanced in the new conical - bottomed FRP water circulation system designed and fabricated in the laboratory. In view of the rigid body structure and small fins of seahorse, a simple cost-effective method of tagging technique was developed and perfected for the seahorse, *H. kuda*. Juvenile seahorses were tagged around the neck region (collar tags). About 10,000 fishers residing in coastal villages such as Puthupattinam, Mullimunai, Karangadu, Morpanai were appraised about the release of tagged seahorses and distributed with pamphlets, explaining the importance of tagged seahorses.

The tagging and recapture studies highlighted that the natural growth rate of seahorse (*H. kuda*) in their normal habitat was 4.15 mm/month. The results of sea ranching and recapture of seahorse juveniles indicated that it is possible to enhance their stock in selected marine habitats by producing large number of young ones and sea ranching them.

Pop up Satellite Tagging of Yellowfin Tunas (*Thunnus albacares*) in Oceanic Waters

Pop-up X-tag supplied by Microwave Telemetry Inc. was deployed on yellowfin

Developmental stages in sea horse



Embryo inside the male's brood pouch | 20 days old embryo | Baby just released | One month old baby

Tagging for studying natural growth and migratory pattern

Collar-Tagged seahorses

tuna (*Thunnus albacares*) for the first time in Indian waters by Central Marine Fisheries Research Institute during December 2011 to February 2012 to understand the migratory movements of this species in oceanic waters near and away from Indian waters. A total of 15 tags were deployed, in two phases along the Bay of Bengal and the Arabian Sea with the pop-up time ranging from 4 months to a year. Tagging was done in the Bay of Bengal Region from Visakhapatnam where eight tags were deployed and along the Arabian Sea tags were deployed off Lakshadweep Islands. The tagging programme is funded by INCOIS under the project entitled "Satellite Telemetry studies on Migration patterns of Tunas in Indian Seas" (SATTUNA). With this achievement India joined the elite group of countries engaged in satellite tracking of yellowfin tuna. Earlier report on pop-up tagging of yellowfin tunas were only on six individuals tracked in the Gulf of Mexico using pop-up satellite archival tags during 2009.

Tagged yellowfin tuna released in to the sea

Cost Effective and Rapid Duplex PCR Kit of CMFRI for Early Detection of White Spot Syndrome Virus (WSSV) of Shrimp

White spot disease caused by White Spot Syndrome Virus (WSSV) is one of the major threats faced by the shrimp farming industry. As there is no cure for this disease, stocking disease free larvae is one of the management measures recommended to prevent critical transmission of the virus. During the culture period it is necessary to monitor the disease status routinely. Use of PCR assisted diagnosis has many advantages over the conventional methods. Since PCR can amplify oven a single strand of DNA into millions of copies within hours, even a single bacterial cell collected from the infected fish could be used directly for the identification. Thus considerable time can be saved. The PCR technique will detect early infection and enable the farmers to adapt a suitable strategy to minimize losses. Diagnosis relying only on the appearance of white spots does not help as by then the shrimps will die within a few days resulting in severe losses. CMFRI has designed a duplex PCR for detection of WSSV which is cost effective, faster and reliable. This involves the simultaneous PCR screening of different regions of the viral genome with appropriate primers.

Duplex PCR is conducted in a single run, thus, reducing time required for the screening. Since different regions of the viral genome are amplified and checked simultaneously, it has got high reliability also. This technology has been commercialized during 2005 to Microl Remedies, Hyderabad. The aqua-clinic provides screening service to shrimp farmers and hatcheries to select virus free shrimp larvae for stocking at the competitive rates using the kit.

Suggested Readings

A device for breeding and culturing marine fish in open sea, Indian Patent Application No. 31/CHE/2010.

A method and composition for land-based culturing of pearl oyster in marine body and device therefore, Indian Patent Application No 1543/ CHE/2009.

A phytase produced extracellularly from thermophilic bacterium, Indian Patent Application No 203/CHE/2008.

A process to concentrate anti-inflammatory principles from green mussel and a product incorporating these ingredients, Indian Patent Application No 2065/ CHE/2010.

A process to prepare antioxidant and antiinflammatory concentrates from seaweeds and a product therof, Indian Patent Application No 2064/CHE/2010.

A process to prepare naturalised *Artemia francesciana* from Indian subcontinent with high docosahexaenoic acid and trehalose for aquaculture applications, Indian Patent Application No 2063/ CHE/2010.

A product containing anntiinflammatory principles from green mussel *Perna viridis* L. and a process thereof, Indian Patent Application No 2066/CHE/2010.

A process to isolate anti-inflammatory principles from green mussel Perna viridis L., to prepare a stabilized nutraceutical supplement against inflammatory disorders and a product thereof, Patent of Addition: Indian Patent Application No. 5198/CHE/2012.

A product containing anti-inflammatory principles from brown seaweeds and a process therof, Patent of Addition: Indian Patent Application No. 5199/CHE/2012.

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Ayyappan, S., Moza, U., Gopalakrishnsn, A., Meenakumari, B., Jena, J.K., and

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Cement & concrete moulded artificial reef apparatus to aggregate marine fish, Indian Patent Application No. 5197/ CHE/2012.

CMFRI, Cochin (2011) CMFRI annual report 2010 - 2011. Technical Report. CMFRI, Cochin.

Development of galvanized iron cage for finfish culture in open sea. Indian Patent Application No. 5196/CHE/2012.

Formulated feed for marine ornamental fishes and a process thereof, Indian Patent Application No 32/CHE/2010.

Hatchery technology for production of clown fish, Indian Patent Application No 3455/ DEL/05.

Hatchery technology for production of damselfish, Indian Patent Application No 1638/DEL/2004.

In vitro pearl production using marine organisms Global Patent Application No. PCT/IB2006/003299.

MPEDA, Cochin (2012). Dedicated website www.mpeda.com. The Marine Products Export Development Authority, Ministry of Commerce and Industry, Government of India. 2012.

On shore marine pearl culture, Indian Patent Application No 458/DEL/2001.

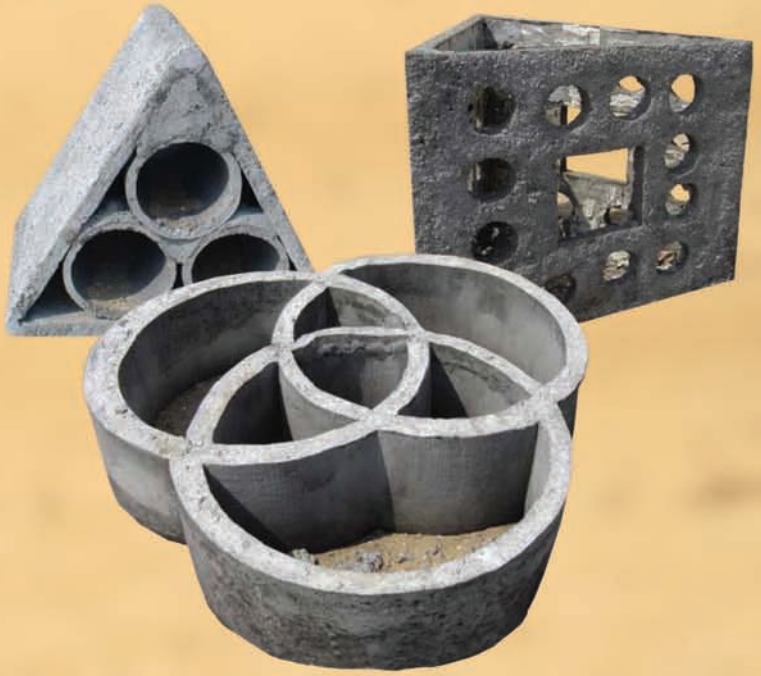
Ravishankar, A., and Archak, S. (2000). Intellectual property rights and agricultural technology, interplay and implications for India. Economic and Political Weekly. 35 (27), 2446-2452.

Marine ornamental feeds are used in the aquariculture of marine ornamental fishes, which include maintenance, breeding, larval rearing, and aquarium keeping. Presently, formulated feed for marine ornamentals is not indigenously produced, and the demand is met through imports with a price tag in the range of ₹ 4000/- per kg. CMFRI has developed ornamental fish feed Cadalmin™ Varna as an import substitute. These feeds cost ₹ 400/- per kg.

CHAPTER 5

Commercialization of IP - Protected Technologies : Bridging the Science and Market

CMFRI has developed Cement & Concrete moulded Artificial Reef modules such as grouper module, well ring module, and reef fish module. Artificial reefs contribute to a great extent for enhancement of various biological resources and thereby increase in fish production. Installation of artificial reefs in the selected coastal districts will increase fish population in the inshore waters and it will continue to increase fish catches in the years after installation. This will lead to an increase in the income of the artisanal fishermen, particularly during the lean seasons. Further, there will be a considerable reduction in scouting time which will save time and fuel costs.



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CHAPTER

Commercialization of IP - Protected Technologies : Bridging the Science and Market

Introduction

Dissemination of IPR enabled technologies is necessary in terms of IP management. Intellectual property is an important and effective policy instrument to a wide range of socio-economic, technological and political concern. The possession of a patent not only confers certain monopoly rights and privileges, but certain obligations and duties also. Patents are grated on two motives:

- To encourage inventions.
- To make use of the invention in commercial scale.

What Happens When a Patent is Not Commercialized or the Monopoly is Abused

- A compulsory license may be granted.
- The patent be revoked.

While enjoying the monopoly of the patent, the patentee is obliged to work the patent in India on a commercial scale to the fullest extent. The patentee is free to commercialize the patent by him/her or through licensees. As ICAR institutes may not be adquate in scaling up the technology to end-users, the technology is either placed in the public domain through open access, or transferred to end-users through commercialization depending on the nature of technology, public need or marketing prospects etc. The commercialization of the IP generated is enabled through license, royalty and/or sale.

Types of Licenses

- **IPR Ownership Outright Sale:** To sell the IP for an agreed consideration where, the person who has generated the technology doesn't hold any more right on it.
- **Exclusive License:** The seller retains ownership of the IP generated, but gives license to a single party for the exclusive exploitation of the technology. In general, exclusive licenses are considered to commercialize the IP-enabled technologies in remote areas offering low incentives and foreign countries.
- **Non-Exclusive License:** The seller retains ownership of the IP generated, but gives license to more than one party for the exploitation of the technology. Fish seed/feed supplements and culture methodologies (with intervention) that are of direct use by the fish farming communities are also

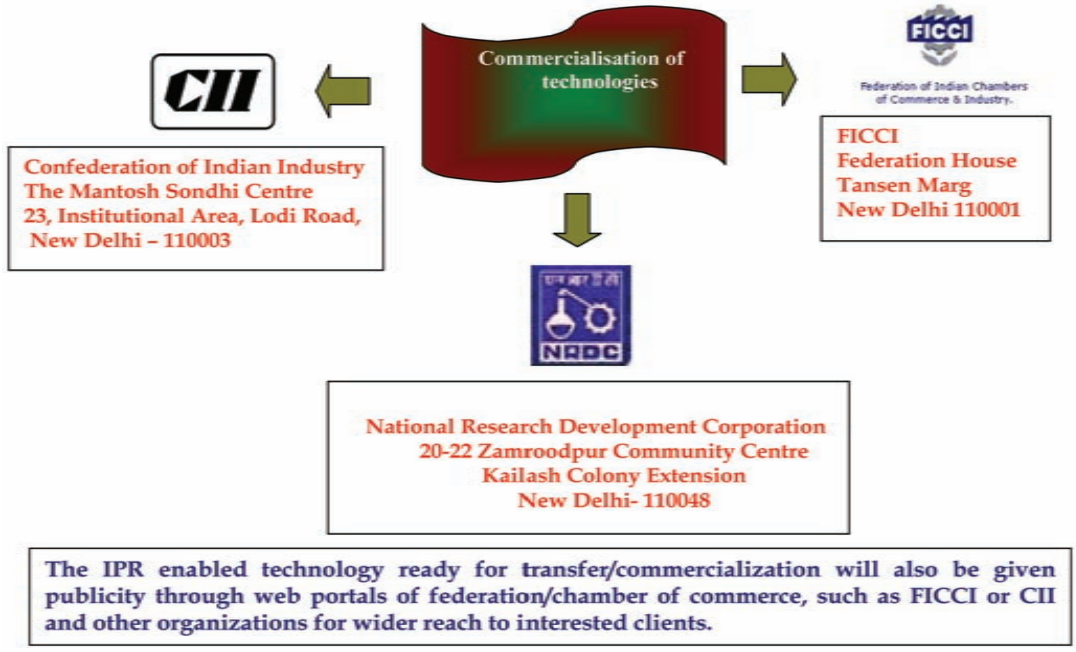
considered for commercialization by non-exclusive means to keep their price under control.

- **Resale License:** The seller retains ownership of the IP generated, but gives license to exploitation of the technology along with a right to resell/ licences to the IPR, to third parties.

There are governmental and non-governmental organizations such as Federation of Indian Chambers of Commerce and Industry (FICCI), Confederation of Indian Industry (CII), National Research Development Corporation (NRDC) that do market watch and identify industries capable to commercialize the market ready technologies. Through their web portals, ICAR is able to give publicity to IP technology developed to identify the company and further commercialize the technology. CMFRI publicizes the technologies for commercialization by inviting the expression of Interests from private farms.

Exclusive Marketing Right

TRIPS requires that member countries of the WTO not having provision in their laws for granting product patents in respect of drugs and agrochemical, must introduce Exclusive Marketing Rights (EMR) for such products, if the following criteria are satisfied: EMR is only a right for exclusive marketing of the product and is quite different from a patent right. It is valid up to a maximum period 5 years or until the time the product patent laws come into effect. The necessary amendment to the Patents Act, 1970 came into force on 26th March 1999. The provision is applicable with retrospective effect from 1st January 1995. As per the 2005 amendments in the Patents Act, the provision of EMR is no longer required. However, these rights were awarded in India from time to time and there have been some litigation as well where the courts came up with quick decisions.



How to Determine the Cost of the IP-Enabled Technology

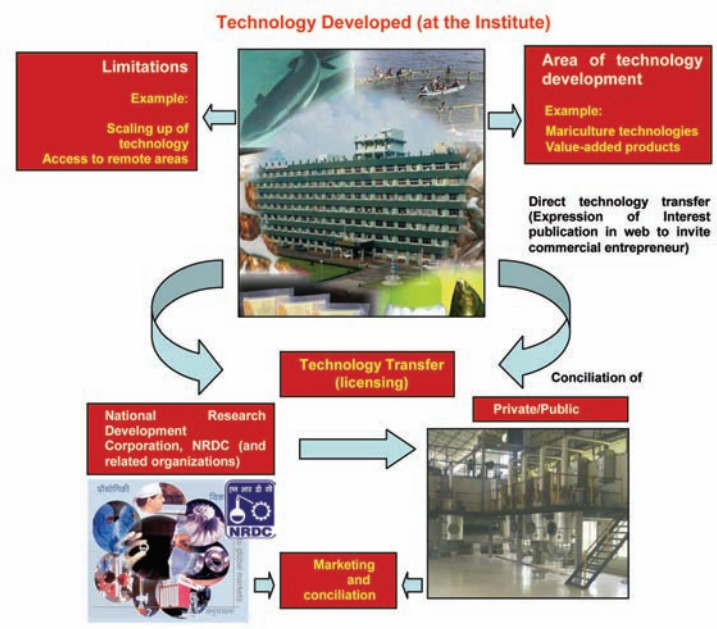
There is no standard method or formulae for assessing the worth of a technology and it varies with likely benefits that may accrue to its end-users. The licence fee/royalty can either be on a fixed basis through negotiations depending on the type of the technology developed. ITMU takes decision about the licensee and the price of the technology.

Factors to be Considered to Fix Price

- Cost of technology production and handling.
- Cost of IPR protection and maintenance.
- Expected adoption level and benefits to the end-users including socio-economic impacts.
- Alternative competing sources.

Mechanism of Transfer of Technology (TOT)

Transfer of intellectual property generated is enabled through mutually agreed terms based on an agreement that outlines each party's expected activities and goals. While commercializing a technology the "Memorandum of understanding (MoU)" and "Memorandum of Agreement (MoA)" should be signed between the parties (CMFRI and private party). In case of a foreign client, a Non Disclosure Agreement (NDA) and MoA are signed by ICAR and the foreign client on all issues relating to contracting, pricing, payment and ownership of intellectual property. A partnership with "for-profit" and "not-for-profit" public or private sector organizations is facilitated on mutually agreed terms. The agreement clearly defines the terms and conditions and limitations, if any, and other relevant points of mutual concern, which include, time-lines for each



Flow chart of technology development to commercialization

activity/area of cooperation/collaboration for each party, provision for mid term review, disclaimers, cost of management of the agreement/ contract, etc. Executing the partnership deals with the application of relevant tools like material transfer agreement, confidentiality agreement, cooperative research agreement, license agreement contract, etc., at appropriate steps should be undertaken.

Public-Private Prartnership (PPP) Enables

- Dissemination of IPR enabled technologies.
- Incubation and up-gradation of the technology before marketing.
- Jointly explore the national and international markets for the IP generated.

Licensing of IPR

What is License?

A license is a permission to do something that, without the license, would be an infringement of IP. Licensor is one who 'license out' the technology, and licensee is one who 'license-in' the technology of interest.

Why Licensing of Intellectual Properties-the Benefits:

- Sharing of risk - manufacturing promotion/marketing of the product
- Revenue generation
- Increase market penetration
- Reducing costs
- Accessing expertise etc.

Prior Steps of Technology Licensing

- Carry out due diligence exercise before licensing in IP.
- Understand the market for the IP and analyze potential benefits
- Exclusivity : exclusive or non exclusive
- Sub licensing - considering both monetary and commercial aspects
- Signed a NDA, before discussing about disclosing your IP.

Essential Elements of License Agreement

There is no full proof standard draft agreement for license – each needs to be drafted based upon the specific requirements of the transaction. However the following essential elements may be considered as guidelines.

- What do you want to license –patent and/ or TM and/or copyright.
- License terms.
- How IP is going to be used / commercialized- timelines involved, if any.
- Exclusivity.
- Term/duration & termination.
- Sub licensing- if yes, on what terms.
- Payment terms (lump sum and/or royalties).
- Warranties.
- Indemnification.
- Confidentiality and non solicitation.
- Governing laws and jurisdictions.
- Dispute resolution.
- Basic (indicative) skeleton of license agreement (parties name and details, recitals, definitions: important terms used are required to be defined, and license grant)
- IP- For private use or commercial exploitation; improvements-if by licensee – 'license back' provision
- Extent of grant-importation of the related products allowed of not
- Exclusivity/non exclusivity: If so-whether worldwide or is restricted to specific territory
- Sole license or not
- Sublicensing, and then on what terms.
- Compensation terms: Lumpsum and /or royalty. In case of sub licensing- royalty

arrangement; % increase in royalty after certain period.
- Sales target, if any (in case of default, further course of action and 'exit root' when will trigger).
- Reports and audits (monthly, quarterly or annually).
- Obligations of the parties on disclosure and assistance in commercialization/ exploitation of IP with respect to enforcement of IPR, Covenant to Exploit, and improvements/modifications ('cross licensing', 'license back' clause).
- Term and Termination (Initial term/ duration – renewal provision; termination clause- 'mutual exit root'- notice period
- Confidentiality
- Non compete – could be general for some period or territorially specific perpetually - should survive termination.
- Non Solicitation: other party should not solicit your employee (s)/ scientist(s)/key personal(s) –should survive termination.
- Conflict resolution (provision for mediation – time/period specific, provision for arbitration, and applicable Arbitration laws).
- Governing Laws is most important and often ignored by the parties. It is, therefore, imperative to consult a concerned lawyer/advocate before accepting other jurisdiction (other than India).
- Other common miscellaneous clauses – severance, notices, entire agreement etc.

Compulsory Licensing

Patents are granted to encourage the inventors to disclose their inventions and also to grant them monopolistic right to exploit the invention. However, there has always been a danger that the patentee will abuse the monopoly granted to him. The patent is granted not only for the benefit of the patentee, but also for the benefit of the public at large. The inventor of a revolutionary new algorithm discovers that his invention may infringe a previously held patent, whose owner does not use the invention but refuses to grant a licence. A company holding a valuable patent obtains multiple patents on similar technologies to prevent other companies from entering the market. The public interest in all these situations could be advanced by forcing the patentee to grant a licence, but only at the expense of the patentee's exclusive rights. Compulsory licensing occurs when the state requires a patentee to licence his patent to another. Compulsory licensing is typically allowed when the patent is not being worked, when a dependent patent is being blocked, or when the patent relates to food or medicine. The objective of Patent Grant in India is to ensure that the inventions are worked in India on a commercial scale and to the fullest extent without any undue delay. Accordingly, any interested person after expiry of 3 years from grant of patent, may make an application to the Controller for grant of compulsory license on the grounds that the (a) reasonable requirements of the public with respect to the patented invention have not been satisfied; (b) the patented invention is not available to the public at a reasonable price and (c) the invention is not worked commercially to fullest extent in territory of India (vide section 84(1) of the Indian Patents Act 1970). The circumstances constituting "failure to meet the reasonable requirements'' of public in respect of a patent are as follows:

- Inadequate manufacture in India or failure to grant licenses on reasonable terms within a period of 6 months from applying by the applicant resulting in prejudice to an existing trade or industry or its development, or to the establishment of a new trade or industry

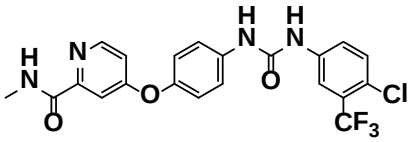
in India, demand for the patented article not being met adequately, failure to develop an export market for the patented articles made in India, prejudice to the establishment of commercial activities/ establishment or development of trade or industry in India; (ii) Non-working of the patent in India on a commercial scale; (iii) Demand for the patented articles being met by importation from abroad; and (iv) Commercial working of the patented invention in India being hindered or prevented by import of the patented articles from abroad.

- Grant of Compulsory license is for the remaining term of patent unless a shorter period looks reasonable and required in case to the Controller. While granting a compulsory license reasonable royalty is also paid to the patentee having regard to nature of invention, its utility, expenses incurred in maintaining patent grant in India and other factors.

India's First Compulsory Licensing Order over Bayer's patent: Natco Pharma Ltd v Bayer Corporation—Compulsory Licence Application No 1 of 2011 (Controller of Patents, Mumbai)

Natco is the first Indian case that has invoked section 84(1) of the Indian Patents Act 1970. Section 84(1) encompasses the law relating to compulsory licensing. Provisions on compulsory licensing, including section 84(1), were enacted by the Patent (Amendment) Act 2002, which replaced earlier compulsory licensing provisions, in order to facilitate Indian patent law's compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organization to which India is a signatory.

Bayer, a subsidiary of the German pharmaceutical giant Bayer AG, is globally well reputed for the invention and manufacture of innovative drugs. In the 1990s, Bayer invented a drug, Sorafenib (carboxy diphenyl substituted ureas), which is used for treatment of advanced renal cell carcinoma (kidney cancer) and hepatocellular carcinoma (liver cancer). Sorafenib is not a life-saving drug but a life-prolonging drug, which extends life by 4 to 5 years for kidney cancer patients and 6 to 8 months for liver cancer patients. Bayer initially made a patent application for the drug before the US Patent and Trademark Office in 1999. Subsequently, by way of an international application under the Patent Cooperation Treaty, Bayer's application entered the national phase of registration in India during 2001 and was accorded protection in 2008 as Indian Patent No 215758. In 2005, Bayer had developed and started marketing the drug internationally under the market name Nexavar. On receipt of regulatory approval for importation, the drug was later launched in India in 2008. The cost of the drug in India for a month's treatment amounted to INR 2,800,428. Citing the high price and the fact that the drug was not fully marketed across India, the Indian generic drug manufacturer Natco Pharma Limited sought a voluntary licence from Bayer in 2010. Natco proposed to manufacture and then market the drug for INR 8,800—a fraction of Bayer's cost for a month's therapy. The request for the voluntary licence was refused. Consequently, once 3 years had elapsed from the date of grant of the patent, Natco applied for a compulsory licence under section 84(1) in August 2011. Compulsory licence is a legal instrument designed to force intellectual property owners to license out their statutorily granted right to interested third parties capable of manufacturing the



4-(4-(3-(4-chloro-3-(trifluoromethyl) phenyl)ureido) phenoxy)-N-methylpicolinamide
NEXAVAR

patented product at cheaper prices.

The Controller of Patents (Intellectual Property Office, Mumbai) has granted the first Indian compulsory licence over Bayer's patent for the cancer drug Sorafenib on grounds of Section 84(1)(a), (b), and (c) under

- non-fulfilment of reasonable requirements of public with respect to the patented invention
- non-availability of the drug at a reasonably affordable price, and
- non-working of the invention in India (Section 84 of the Indian Patents Act) (Rajasingh, 2012)

The Controller found that all the three criteria above were satisfied in this case, namely: (1) that since Bayer supplied the drug to only 2% of the patient population, the reasonable requirements of the public with respect to the patented drug (Nexavar) were not met; (2) Bayer's pricing of the drug was excessive and did not constitute a "reasonably affordable" price. It charged ₹ 2.8 lakh for a month's supply of the drug, whereas Natco was willing to supply the same quantity at ₹ 8,800 a month; (3) Since Bayer did not manufacture reasonable quantities of the drug in India, it could not be said to have complied with the "working" requirement under the Indian Patents Act.

The order marks a watershed in the history of Indian patent law. Patents may now be more palatable to critics, if their worst monopoly effects can be successfully moderated through instruments such as compulsory licensing. The Hindu ran an excellent editorial by Ananthakrishnan, where he notes: "……Mere application of the test of reasonable price in a country with a weak social health insurance infrastructure provides a strong argument for compulsory licensing in the case of Nexavar, the patent for which is held by the German multi-national company, Bayer. At present a month's treatment regime of 120 tablets costs ₹ 2.84 lakh, but manufacture under compulsory licensing will slash it to ₹ 8, 880. The Indian applicant has been granted the licence till the expiry of the patent in 2021. The use of compulsory licensing is bound to raise the temperature in the pharmaceutical industry and be dubbed a move that will stifle innovation. But that would be ignoring the point that it is perfectly legal, and is in fact provided for in the patents regime to balance public interest and corporate profits……." Nata Menabde, India representative, WHO, says, "India has taken a good political stand on compulsory licence and we respect that move. Compulsory License is a very good tool in the hands of governments and they must use it to ensure that health of the people comes before any other rights."

The ruling is a landmark precedent on access to medicines in India as the abuse of patent rights has been checked through the issuance of a compulsory licence for the first time. A few days after this judgment, Swiss healthcare major Roche Holding AG released the news of its collaboration with an Indian pharmaceutical company to repackage and sell its cancer drugs at a low and affordable cost.

Natco is now free to manufacture and sell a generic version of Nexavar, but will have to pay a 6% royalty on the net sales (every quarter) to Bayer. Further, it can only charge ₹ 8800 for a monthly dose (120 tablets) of the drug. In its written submission, Natco also committed to donating free supplies of the medicines to 600 needy patients each year and this commitment has also been recorded in the compulsory licence order.

What are the Points Need to be Considered to be Included in the MoU and MoA

1) The Intellectual Property Rights shall lie with ICAR (the institute concerned).

2) The manufacturer will not sub-license the ICAR (the institute concerned) technology to another party if agreed upon during signing of MoU and MoA.

3) The assigner and the manufacturer shall sign this agreement to maintain close liaison and co-operation for taking up production technology promoted by the Institute for which the Institute concerned provide necessary know-how and guidance for commercial prototype production on payment of institutional fee and training fee as specified or as decided by the Institute. The second party (private) may sign the MoA by paying a token Institutional Fee (if applicable) for manufacturing of the identified technology. The MoA shall be valid for a fixed period of years from the date of signing the MoA, and can be further extended on mutually agreed terms.

4) The Institute reserves the right to allot the technology to different manufacturers on a non-exclusive license basis, if required. In general, the manufacturer shall pay a fixed amount as license fee, as jointly fixed by the two parties or royalty (for example @ 2-6% of the cost of the sale) (to be decided by the ITMC of the institute concerned) for a specified period of time from the commencement of commercial production of the technology.

5) The institute shall make available on cost basis the details of the technology in the form of prototype and/or specifications and other technical details for commercial prototype development or manufacturing of the prototype.

6) The agreement can be terminated if there is any violation of the terms and conditions, quality and timeliness etc. as may be determined by the institute.

7) However, as no standard formulae are available or can be provided for all ICAR technologies and situations, the ITMC at the institute level determines the license fee and/or royalty taking into account of cost of technology, impact of technology on market end-users and socio-economic impacts of IP.

Conclusions

Commercialization of IP-enabled technologies is an absolute necessity to transfer valuable technologies developed in the institute laboratories to the society for greater benefit of mankind. Scientists must be proactive to translate the techniques developed in the laboratories to technologies for wider applicability of our scientific

outputs. In this connection this is also to be remembered that ICAR (and CMFRI being an institute of ICAR) is a public sector organization, and is for the benefit of farmers and society at large. Our primary aim is not to earn royalty or huge downpayment, but to disseminate the technology for the benefit of farmers, end-users, and the society.

Suggested Readings

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Pop-up X-tag supplied by Microwave Telemetry Inc. was deployed on yellowfin tuna (Thunnus albacares) for the very first time in Indian waters by Central Marine Fisheries Research Institute during December 2011 to February 2012 to understand the migratory movements of this species in oceanic waters near and away from Indian waters. A total of 15 tags were deployed in two phases along the Bay of Bengal and the Arabian Sea with the pop-up time ranging from 4 months to a year. Tagging was done in the Bay of Bengal Region from Visakhapatnam where eight tags were deployed and along the Arabian Sea tags were deployed off Lakshadweep Islands. With this achievement India joins the elite group of countries engaged in satellite tracking of yellowfin tuna.

CHAPTER 6

IPR and Aquatic Biodiversity

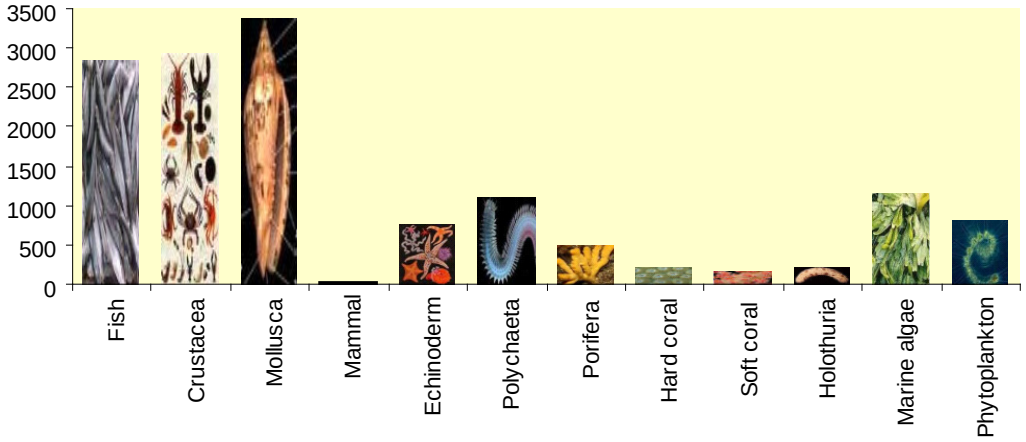
Long-chain polyunsaturated fatty acids (LC-PUFAs), viz., eicosapentaenoic acid (EPA, 20:5n-3), and docosahexaenoic acid (DHA, 22:6n-3) are widely available in a large variety of marine organisms. Methods to develop polyunsaturated fatty acid concentrates from marine sources by chemical and lipase-catalyzed procedure were optimized for use as a source for enriching larval feeds and broodstock diets of marine finfish and crustaceans and as nutraceutical supplements. In this process marine fish oil was enriched through chemical, biochemical and microbiological procedures to formulate EPA rich emulsion.

IPR and Aquatic Biodiversity

6
CHAPTER

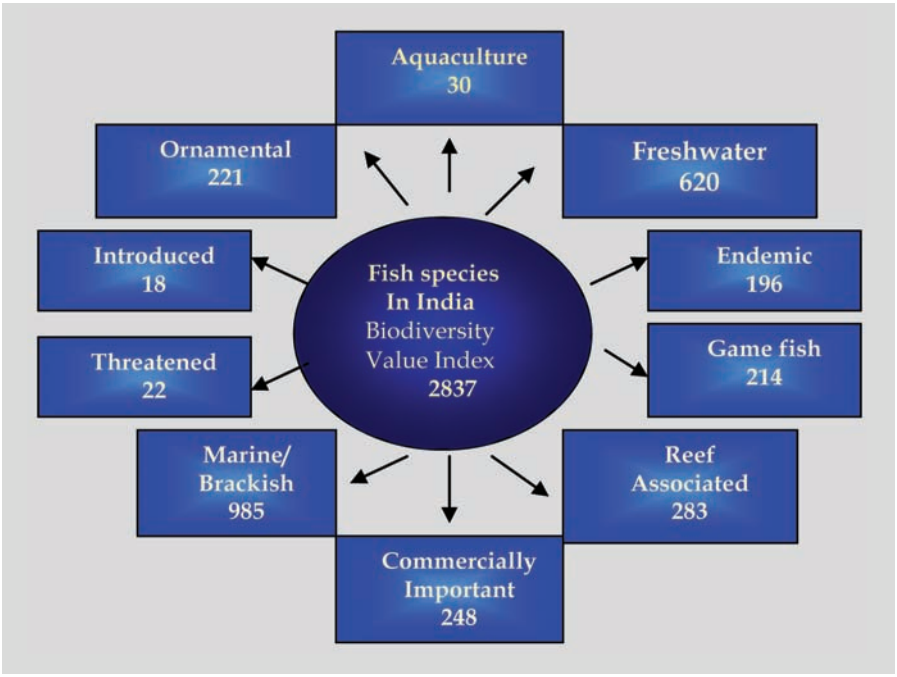
Introduction

India is the seventh largest country in the world and Asia's second largest nation. According to Ministry of Environment and Forest Report, the country is estimated to have over 49,219 plant species and 81,251 animals representing 12.5% of the world's flora and its fauna. The diversity of India is high enough to enjoy the position as one of the 12 mega diverse countries of the world. Meanwhile, it has three biodiversity hotspots of total 25 with 33% endemism in plants.



Number of marine species of some major groups of organisms from Indian EEZ

Indian Ocean accounts for 29% of the global oceans, 13% of marine organic carbon synthesis, 10% of the capture fisheries, 90% of the culture fisheries, 30% of coral reefs and 10% of the mangroves. India has rich aquatic biodiversity spreading across different ecosystems hold about 12% of the world's fishes with about 2200 species. The number of fish species identified from India is given in the following diagram.



Source: First National Biodiversity Strategy and
Action Plans to the Convention on Biological Diversity

Other than finfish species, crustaceans, molluscs, reptiles and mammals form the nekton of marine environment. The approximate number of species of some major groups identified from Indian seas is presented under the diagram shown above.

Benefit From Biodiversity and the Need to Protect

Oceans account for about 90 per cent of the biosphere and cover 71 per cent of the earth's surface. Marine species significantly differ among each other than the terrestrial organisms. Only five out of the 33 existing animal phylum are not represented in the marine environment, while 13 of them are exclusively marine (Mart´ınez Prat, 2002). As a result, genetic, biochemical and physiological animal diversity is much larger in the oceans than on land. Another factor that contributes to marine biodiversity is the difference in communities contained at different photic zones, other than differential pressure and food availability. 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 (Mart´ınez Prat, 2002).

The marine biodiversity benefited mankind through direct and indirect economic benefits and industrial means. Biodiversity forms the foundation of human civilization and the biological capital of our planet by providing us food, shelter, cloth, medicine, warmth, energy, industrial products, and recreation among many others. The indiscriminate exploitation of nature and marine biological diversity leads to loss of species, which in turn results in change of

the ecosystem and the whole biosphere. As biological and physical processes are interactive, the loss of biodiversity may cause further environmental changes, which may prevent recovery of lost species/ diversity. The diversity of marine system is less known as compared to the terrestrial counterpart because of the difficulties in sample collection and underwater surveys, so is the change in diversity and its effect on ecosystem too. At this point arise the need of conservation, natural resource managment and marine biodiversity protection.

The Biodiversity Act is "to provide for conservation of Biological Diversity, sustainable use of its components and equitable sharing of the benefits arising out of the use of biological resources and for matters connected therewith or incidental thereto". Property rights in marine ecosystems can control both use and conservation. The scope of the Act lies in individual species, the water body where the species live or the different types of use of the organism or the system.

Fish Genetic Resources: Consultative Group on International Agricultural Research (CGIAR) Policy Framework

Cultures of the marine coastal populations are directly linked to marine biodiversity. Many of them have developed management systems that, while ensuring the conservation of marine biodiversity, used several traditional practices using marine resources. For example, coastal peoples of northwestern America use marine algae for wound healing and health care purposes. Traditional healing practices in the Maldives rely both on terrestrial plant species and many marine species of fish, coral and seaweed. In Brazil, traditional zootherapy knowledge of the artisanal fishing community is well known for using marine organisms for use as folk medicine (Medeiros Costa-Neto, 2000). Marine diversity is increasingly feeding a myriad of industries. On the one hand, many industries are turning to the sea, expecting that its huge genetic, biochemical and physiologic diversity will contain useful substances.

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 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. However, 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 in-house 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 (Correa, 1998).

Biological Diversity Act (2002)

Biological Diversity Act was enforced on 15th April 2004, and National Biodiversity Authority (NBA) came into existence from 1st October 2003. NBA has 16 members. State Biodiversity Board, and Biodiversity

Management Committee (Local Biodiversity Fund/local levy, People's biodiversity registers) are other entities work under NBA to look into the national and local biodiversity rules, laws, and regulations.

The regulatory provisions of NBA are summed as follows:

- No person referred to in sub section (2) of the National Biodiversity Act shall, without previous approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio survey and bio utilization.
- Results of research not to be transferred to certain persons without approval of National Biodiversity Authority (for the purposes of this section, "transfer" does not include publication of research papers or dissemination of knowledge in any seminar or workshop, if such publication is as per the guidelines issued by the Central Government).
- These provisions shall not be applicable in case of collaborative research projects if these projects, and must conform to the policy guidelines issued by GOI/ approved by the GOI.
- No person, who is a citizen of India or a body corporate, association or organization which is registered in India, shall obtain any biological resource for commercial utilization, or bio survey and bio utilization for commercial utilization except after giving prior intimation to the State Biodiversity Board concerned.

Transfer of Resource/ Knowledge

No person who has been granted approval under section 19 of the National Biodiversity Act shall transfer any biological resource or knowledge associated thereto which is the subject matter of the said approval except with the permission of the National Biodiversity Authority. The National Biodiversity Authority shall while granting approvals under section 19 or section 20 of the National Biodiversity Act ensure that the terms and conditions subject to which approval is granted secures equitable sharing of benefits arising out of the use of accessed biological resources, their by products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.

Regulations- IPR

No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application. The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights. The provisions of this section shall not apply to any person making an application for any right under any law relating to protection of plant varieties enacted by Parliament. Biological Diversity Act explains "commercial utilization" as "end uses of biological resources for commercial utilization" such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture,

horticulture, poultry, dairy farming, animal husbandry or bee keeping.

Punishments

Whoever contravenes or to or abets the contravention of the provisions of section 3 or section 4 or section 6 shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees and where the damage caused exceeds ten lakh rupees such fine may commensurate with the damage caused, or with both. Whoever contravenes or attempts to contravene or abets the contravention of the provisions of section 7 of the Biological Diversity Act or any order made under sub section (2) of section 24 shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five lakh rupees, or with both. Offences to be cognizable and non-bailable.

The notification of Ministry of Environment and Forests dated 8th November 2006 is as follows:

Ministry of Environment and Forests Notification

New Delhi, the 8th November, 2006

S.0.1911(E). - In exercise of the powers conferred by clause (a) of sub-section (3) of section 5 of the Biological Diversity Act, 2002 (18 of 2003) the Central Government hereby makes the following guidelines namely:-

(l) These guidelines may be called the Guidelines for International Collaboration Research Projects Involving Trasfer or Exchange of Biological Resources or Information relating thereto between institutions including government sponsored institutions and such institutions in other countries.

(2) They shall come in to force on the date of their publication in the Official Gazette.

(3) In view of the fact that collaborative research projects have been exempted from obtaining approval of the National Biodiversity Authority established under section 8 of Biological Diversity Act, 2002, (hereinafter referred to as the Act) and that the need for transfer and exchange of biological resources cannot be ruled out in such projects, sponsored under the bilateral and multi-lateral agreement, Memorandum of Understanding and work plan etc. under the International Collaborative Research Projects, these guidelines are hereby notified by the Ministry of Environment and Forests in compliance with the said provisions of the Act and for such research projects.

4(1) The collaborative research project shall clearly state in the proposal:

(a) The key investigator(s) in each of the collaborating institution, who shall be responsible for all compliances and in case of any contravention, this person will be held responsible. Changes in the identity of the key investigator should be intimated to the concerned Department/Ministry of the Central Government;

(b) Details of biological resources occurring in India and knowledge associated thereto, intended to be exchanged or transferred under the project, such as biological name, quantity, purpose, source, place of collection and such other activities;

(c) Value addition, if any, to the biological resource and associated knowledge;

(d) In case the biological resource referred to in (b) above has any special status under any law in force in India or any international agreement, the details of

the same may be provided, including necessary clearances from competent authority.

(2) The collaborators shall abide by the provisions of existing national laws, regulatory mechanisms and international agreements or treaties.

(3) The biological resource (s) and associated knowledge intended to be exchanged or transferred under such projects shall be used only for the research purpose specified in clause (b) of sub-paragraph (1) above.

(4) The quantity of biological resource(s) intended to be transferred or exchanged shall be limited to the quantity necessary for experimental purpose, as specified in the proposal and as per the access and material transfer guidelines developed by National Biodiversity Authority.

(5) In case the results of research from this project subsequently prove likely to' lead to any Intellectual Property Rights, the collaborating partners shall enter into a fresh agreement with National Biodiversity Authority (established under section 8 of the Act) to ensure sharing of benefit in accordance with provisions of section 6 of the Act, prior to filing of the application for Intellectual Property Rights(s).

(6) The voucher specimen of the biological resource occurring in India transferred or exchanged under the project shall be sent to the designated repository in accordance with section 39 of the Act.

(7) In case the collaborative research projects involve exchange and transfer of dead or preserved specimen(s) and /or herbarium(s) of India on loan or on any other terms, for taxonomic studies as required by bona-fide scientists/ professors of recognized universities and Government Institutions of India who are engaged in pure classical taxonomic studies, this shall be done with the approval of concerned Departments/ Ministries of the Government of India.

(8) Collaborators shall not communicate or transfer research results of the collaborative project to any third party in any manner without entering into an agreement with the National Biodiversity Authority for this purpose.

(9) Publication of Research paper(s), book(s), bulletin(s), registered accession(s) and output(s) based on the results of the research of such projects, shall not be done without the prior approval of the Indian collaborator.

(10) During the course of the implementation of the project, any knowledge associated with exchanged or transferred biological resource from India shall be reported to National Biodiversity Authority for facilitating documentation of such knowledge.

(11) Any publication(s) relating to knowledge associated with biological resource exchanged and/or transferred from India under the collaborative project shall acknowledge the knowledge holders from whom this knowledge was obtained.

(12) Any new taxon, breed(s), genetic stock(s), culture(s), strain(s) or line(s) discovered or developed through the project shall be reported to the National Biodiversity Authority and a voucher specimen shall be deposited with the designated repository in accordance with the Act.

(13) The collaborative research project shall have to be approved by the concerned Ministry/Department of the State or the Central Government.

(14) A copy of the approval along with all relevant details shall be sent to the Biodivesity Authority.

(15) For more details about Bioiogical Diversity Act, 2002, National Biodiversity Authority and related issue log on www.nbaindia.org.

[F. No. 2.6/4/2006, CSC]

DESH DEEPAK VERMA, Jt, Secy.

ICAR Policies with respect to TRIPS and Fisheries

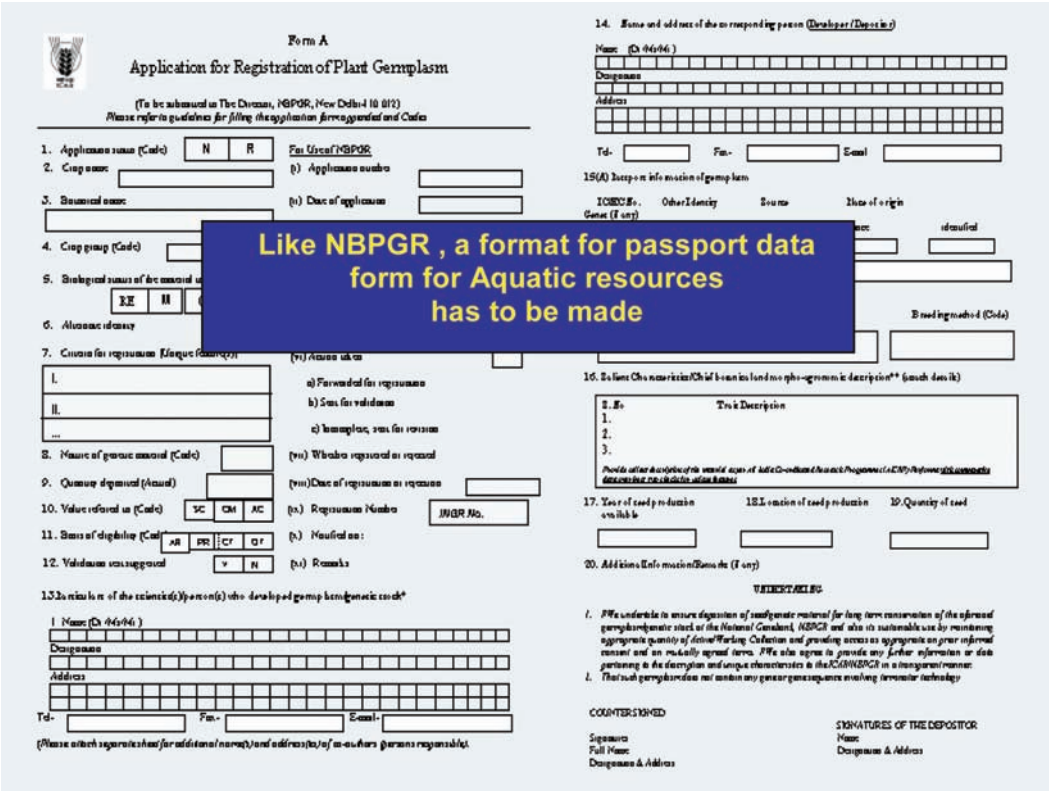
With respect to the biological material (e.g., fish) used in various invention/s specific attention need to be given to the source or geographical origin of biological material used in the invention and the same need to be disclosed in the patent application. The reference samples deposited at the Genetic Resources Bureaus of ICAR will be helpful for internal reference (ICAR, 2006). However, in case of any litigation it is likely that the evidence in the form of such duly characterized and documented referral sample can be held valid at the discretion of a Court of Law. As referred in the ICAR Guidelines for Intellectual Property Management and Technology Transfer/ Commercialization, all ICAR institutions must take individual initiative of depositing a referral sample at the respective National Bureaus (e.g., fish genetic resources) before filing a patent for any invention based on biological material. Traditional knowledge in fisheries also comprises an important share of IP as outlined under the TRIPS

Marine ornamental fish: Clownfish (*Amphiprion* sp) or Sea Anemone fish

Agreement. Accordingly, ICAR shall also disclose the traditional knowledge related to the innovations made in its set up in all patent/ IPR applications to the best of its knowledge and information.

In this context it requires to be mentioned that isolation of indigenous genes from fish or marine organisms and their application for specific target traits will have special significance and prospects. Therefore, ICAR genetic resource bureau for fish will make efforts to register document and index these knowledge items in public domain. This is to discourage any patenting of the public domain traditional knowledge.

Improved breeds/ strains of fish cannot be protected in India as patents or variety protection. However, these resources constitute valuable assets in ICAR and India. ICAR has a system in place for plant germplasm registration and documentation at its National Bureau of Plant Genetic Resources (NBPGR) for long. However for elite fish genetic material in the public domain, there is no IPR enabling provision under the existing Indian laws nor is there any provision for the registration and documentation of the breeds and strains of fish developed by ICAR. To check their misuse or exploitation, "ICAR will develop a system of their registration and documentation, at the respective National Bureaus of Animal and Fish Genetic Resources for quickly placing them through disclosure in the public domain thereby forestalling any unforeseen patenting in other countries ….and to establish a system



What can be the format to register elite fish varieties?

of their registration and documentation. It will suitably extend the existing system to register and document the elite and new breeds/strains of fish developed in ICAR, at the National Bureau of Fish Genetic Resources (NBFGR)" (ICAR, 2006).

Need for Registration of Aquatic Diversity

As per Indian Patent Act, Section 3(j), plants and animals in whole or any part thereof other than GMO and essentially biological processes for production or propagation of plants and animals are not patentable in India. However, IPA allows for patenting whole organisms like transgenics, with human intervention. To pre-empt any unforeseen grant of patents on fish, including the improved breeds/strains, there is a need to establish a system of their registration and documentation to suitably register and document the elite and new breeds/strains of fish developed in ICAR at National Bureau of Fish Genetic Resources.

Suggested Readings

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भाकृ अनुप
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www.cmfri.org.in E mail : director@cmfri.org.in

Cadalmin™ Green Algal extract (Cadalmin™ GAe) is an anti-arthritic and 100% vegetarian nutraceutical from seaweeds or marine macroalgae (Indian Patent Appl. No. 2064/CHE/2010; 5199/CHE/2012). Cadalmin™ GAe is a pure natural and 100% vegetarian product, with its therapeutic values, is an import substitute with an international appeal, providing great market potential especially for the large vegetarian population in India and abroad. The unique biochemical engineering techniques adopted to retain the anti-inflammatory activities in the preparation of Cadalmin™ GAe assures higher shelf life. This is the first product developed by an ICAR institute from seaweeds for use against arthritis and joint pain.

CHAPTER 7

Marine Resources: An Emerging Sector Leading to Intellectual Properties

Seaweeds or marine macroalgae contributes about 10% towards the marine natural products isolated from oceanic environment. Padina tetrastomatica is phaeophytan seaweed abundantly available at Gulf of Mannar region of India. A total number of 6028 patents have been granted on various aspects of marine macroalgae till 2011 (source: http://www.thomsoninnovation.com). CMFRI identified the seaweeds which are natural bounty of sea, to possess valuable compounds that can offer relief to arthritis and associated joint pain.

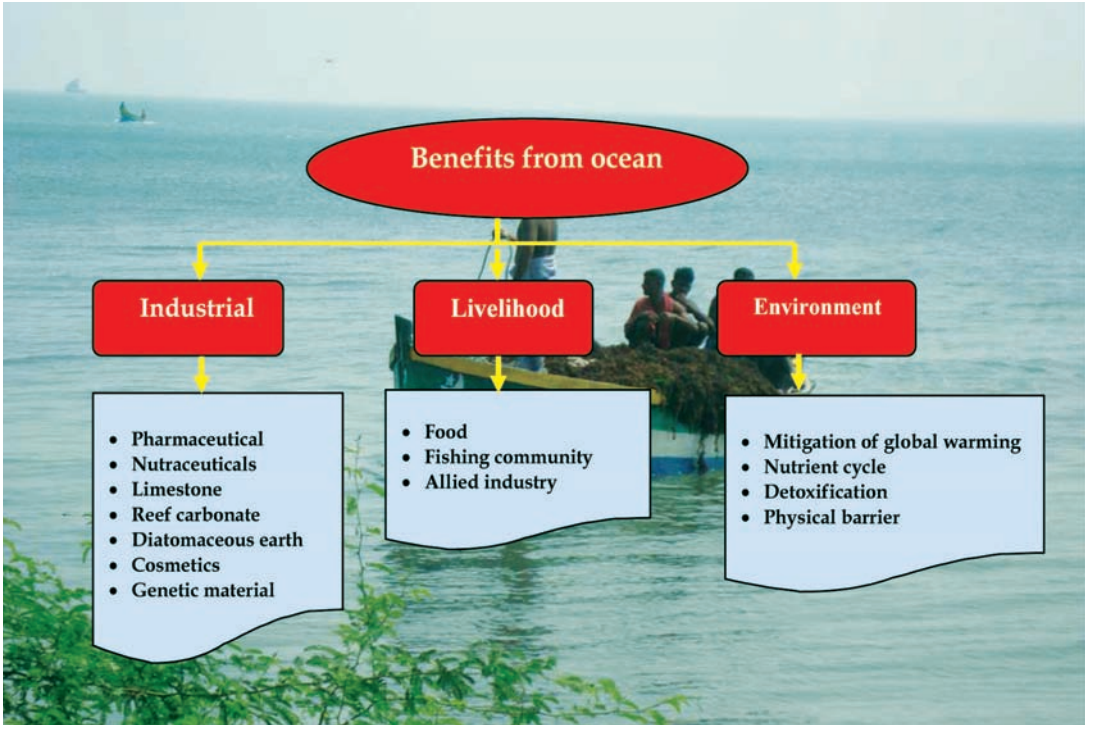
Marine Resources: An Emerging Sector Leading to Intellectual Properties

7
CHAPTER

Introduction

The great ocean forms more than 70% of the earth, though we know to some extent of the coastal and the upper layers of the ocean, the 80 percent of the ocean, which constitute 62 percent of the entire earth's surface, are unknown.

The marine environment provides a wide range of goods and services essential for human life. Other than food, marine ecosphere constitutes a vast reservoir of valuable compounds with wide range of bioactivities against several life-threatening diseases.



Marine Fisheries of India

India is bestowed with 8219 km of coastline with 20-lakh square km of exclusive economic zone (EEZ) for fishing around coastline. High priority is being offered to marine fisheries development with the support for production, and marketing the fishes as well as offering, suitable training for fishery industry. The harvestable potential of marine fishery resources from Indian EEZ is 3.93 million tones. Indian marine capture fisheries production has grown 6-fold from 0.5 million tones in 1950 to 3.16 million tones in 2009. The production has fluctuated around 2.7 mt in the last decade and has crossed 3 million tones in 2008. Due to the growing food demands prices will continue to increase for fisheries commodities and a sustainable fisheries can make profit even with stagnant catches.

Marine fish production over the years and landings of marine fishes during 2010-11 (Ayyappan *et al*, 2011; CMFRI Annual Report 2011)

The fisheries sector is contributing very less (around 1%) compared to other sectors in respect to GDP. The fish production has increased compared to other agricultural products but the consumption per capita per annum is still at 9 kg, even in small quantities, fish can have a significant positive impact on a healthy diet. The export of marine products is showing increasing trend and the money earned from the sector too. The export of the commodity from India has shown an ever time record during 2008-09 (602835t and Rs. 8607.94 crores). The sector contributes around 4.56% to Agriculture GDP in India. Though the percentage GDP of the sector has

A view of the marine fish landing (*Parapenaeopsis stylifera* at Thottappally, Kerala)

decreased slightly in 2008, the value shows an increase to Rs. 356500 million. Besides its contribution to Indian economy, the sector supports livelihood of more than 14 million fishermen.

IP in Marine Sector

A novel process to produce a product or by-product out of marine resource, or product itself is patentable. Also the pharmaceutical or other properties of bioactive compound(s) that is (are) unknown from marine resource is patentable. Marine organisms have various biotechnological applications in the area of health, environment and mariculture. As compared to terrestrial ecosystem very meager is known and explored from marine environment probably because of the difficulty in reaching the depths.

The areas of patenting in fisheries sector includes

- Technologies and methodologies in fishing, processing, and aquaculture/ mariculture (with intervention)
- Pharmaceuticals
- Nutraceuticals
- Cosmetics
- Food and feed
- Bioactive compounds

The percentage contribution of technologies patented under the three major divisions of fisheries sector include 21% on aquaculture, 25% on fishing, and 54% on fish processing (Ninan et al, 2005). An increasing trend of filing patents after the Indian Patent Act, 1970, and further increase in post WTO era is also noteworthy.

Intellectual Property Rights in Fisheries Sector

Patent statistics revealed that has not been compared with other countries, it is seen that the patenting activity in India has been insignificant as compared to USA, Europe and Japan. The adoption of insignificant number of patent protection in India and licensing of patented technologies is also reflected in the index of patent rights, which is 1.48 in 1990 (Ginarte and Walter, 1997; WIPO, 2011).

In recent times among the Indian organizations, CSIR along with other private industries are the major patent applicants in India and US, the rest of patent applicants are foreign individuals. There is also lack in continuity in patenting activity for the last four decades from 1920-1950 in the field of aquaculture. However, in recent years (after 1996) there are incremental trend in patent filing in ICAR institutes including fisheries. Among fisheries, a maximum of 55% of patents have been granted in the field of processing technology followed by 24.5% in fishing technology and about 21% in aquaculture. Among fish processing technology, about 43% of the patents granted to the foreign nationals, and about 15% to CSIR in the subject area of extraction and isolation of polysaccharides and protein from marine organisms, fish oil originated fat liquors, alkaloid from sponge etc. In post WTO era (1996-2000), the average number of patents granted in fisheries discipline is six in a year. Increasing awareness for patent search engines/sites, access to patent information, and the comparatively easier administrative procedures in the amended patent laws are among various reasons for increased patenting activity. In aquaculture too, the majority of patents (45%) granted in India are to the foreign nationals (Ninan et al., 2005). Since the innovations in processing technology can be varied easily in the process patent application area, and are easily imitable towards various directions, there appeared to be greater trend to incline for processing

technology in fisheries subject. Importance of processing technologies with respect to export and trade in and outside India also are the reasons that hold the edge towards patent application in India as compared to other subjects in fisheries like aquaculture, machinery or fishing technology. This is also an example that demonstrates the fact that process patents provides stimulus for dynamic competition wherein the same product is manufactured by different processes. The patents on method for obtaining carrageenan, chitin, phycocyanin, and products from spirulina, polyunsaturated fatty acids, bioactive compounds, alkaloids and other bioprocessed products.

In recent times marine flora have been identified as valuable resources to isolate bioactive molecules for use against different diseases. However, this area is vastly unexploited and after implementation of the product patent regime in 2005, research and patenting activity in this sector could rise. CMFRI has taken the lead to develop a nutraceutical supplement with concentrated anti-inflammatory principles as Cadalmin™ Green Algal extract from seaweeds for use against joint pain and arthritis (Indian Patent Appl. No. 2064/CHE/2010; 5199/CHE/2012). Around 46% of the total patents granted in fisheries sector during the post WTO era (1996-2002) are in processing technology. A total of 27.93% of patents applications related to water treatment, waste water treatment, power and electricity generation from sea waves, river bank protection, manganese nodules, purification of microbes in water, etc., whereas 14% of patent applications relate to aquaculture, and about 12% patent applications relate to fishing technology (Ninan *et al.*, 2005)

Patenting Trend in Marine Sector

Marine species are much diverse with 28 existing animal phyla of which 13 are exclusively marine. Hence, genetic, biochemical and physiological animal diversity is much larger in the oceans/marine environment. Sessile or sluggish invertebrates secrete toxic substances as defensive mechanism and are the prime organisms for bioactive metabolites and potential drugs. Research on anti-cancer agent from marine resource is notably high. Between 1969 and 1995, 63 marine substances were patented as antitumour agents, accounting for half the marine molecules patented for pharmaceutical purposes.

The "Marine Pharmacology Review 2003-2004" shows initial pharmacological results of 166 marine chemicals with

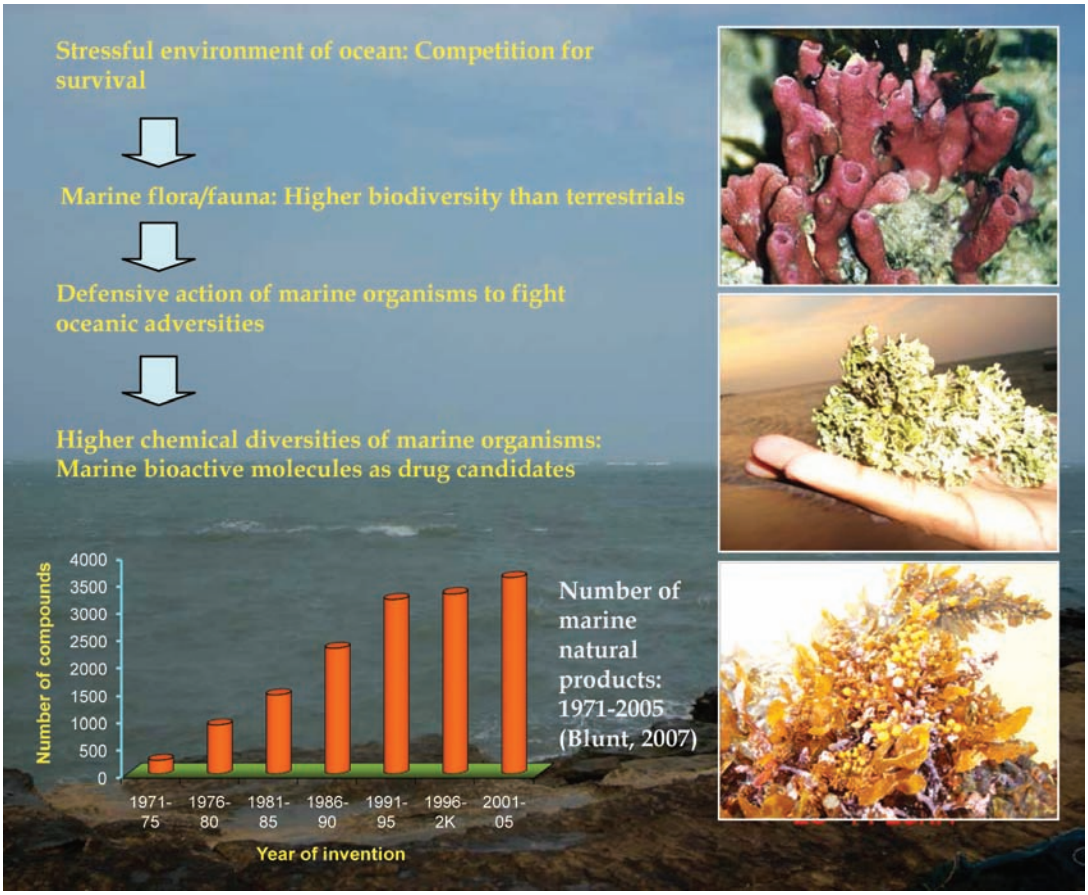
- About 67 marine organisms showing antibacterial, antifungal, antimalarial, antituberculosis or antiviral activities
- About 45 marine derived compounds reported to have significant effects on the cardiovascular, immune and nervous system as well as possessing anti-inflammatory effects.
- About 54 marine derived compounds, which act on a variety of molecular targets with a potential contribution to several pharmacological classes (Source: WWF).

There is a high degree of representation of terrestrial-derived bioproducts, and, therefore, the number of marine natural products that have found their way into pharmacies is thus far small. This has more to do with the relative infancy of marine bioprospecting (than terrestrial bioprospecting). The natural products isolated from marine sources tend to be more highly bioactive than terrestrial counterparts because they have to retain their potency despite dilution in surrounding seawater to be effective in the "chemical warfare"

that allows marine flora and fauna to ward off would-be predators and animals that might attempt to grow over and smother them. Despite lesser attention paid to marine natural products historically, there are notable marine-derived bio products that are commercially available and IP protected.

Bioactive Compounds from Marine Organisms: A Potential Source of IP in Marine Sector

Ocean is a potential source of bioactive compounds, which does not have a significant history of use in traditional medicine as in the case of terrestrial plants (Kamboj, 1999). Previously, the research was focused mainly on terrestrial plants because of their easier availability. The isolation of biologically unique molecules from marine organisms that are not found in terrestrial sources leads to a remarkable progress in marine bioprospecting. The boom of marine bioprospecting began in recent years and 18000 plus natural compounds from marine organisms have been isolated as compared to 155000 terrestrial products (Blunt, 2004; Mayer *et al.*, 2007). Between 1969 and 1995, 63 marine substances were patented as antitumour agents, accounting for half the marine molecules patented for pharmaceutical purposes (Mart´ınezPrat, 2002). There are a significant (and growing) number of marine-derived compounds with pharmaceutical potential in the pipeline.

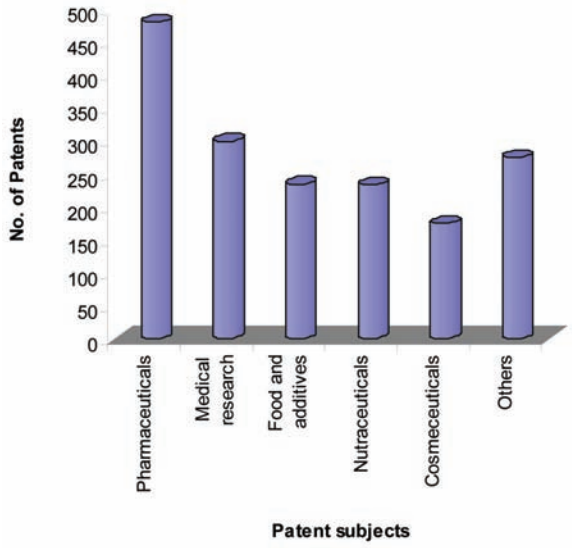


The accompanying table in the next page (modified from one included in Kijjoa and Sawangong 2004) presents the marine-derived potential therapeutic compounds used for drug discovery efforts. Many of these are still undergoing preclinical evaluation, but several others are currently being administered to patients as part of clinical trials.

CMFRI is one of the pioneering institutes to isolate and characterize bioactive compounds with antioxidant, antibacterial, and anti-inflammatory properties from marine flora and fauna, some of them have been protected by patents (Appl. No. 2064/CHE/2010, 2065/CHE/2010, 2066/CHE/2010; 5198-99/CHE/2012). A sampling of some of the most exciting marine based IP protected drug discoveries currently undergoing clinical evaluation are briefly summarized below.

Marine-Derived Drugs

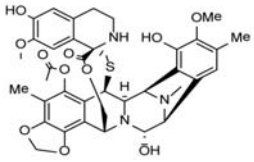
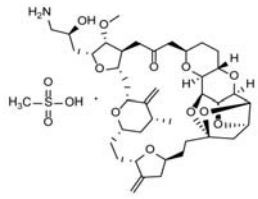
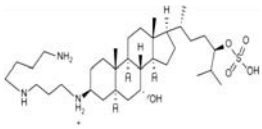
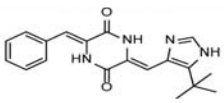
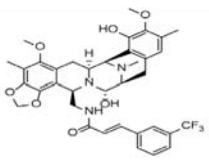
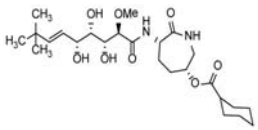
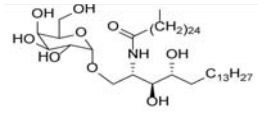
The first modern marine-derived drugs dated back more than 50 years. Werner Bergman extracted the novel compounds spongothymidine and spongouridine

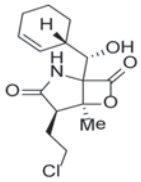
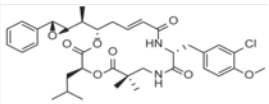


from the Caribbean sponge *Tethya crypta* in the early 1950s. These compounds were nucleosides similar to those forming the building blocks of nucleic acids (DNA and RNA). These natural nucleoside analogs were discovered to have unexpected antiviral properties.

The arabinoside Vidarabine® (ARA-A) and Cytarabine® (ARA-C) (two of the first ever discovered marine drugs) are the compounds extracted from the marine sponge *Tethya crypta*. Vidarabine is patented, and is commonly prescribed for viral infection as ophthalmic ointment, whereas patented Cytarabine® (ARA-C) is a chemotherapy drug. This medicine reduces the growth of cancer cells, and can suppress the immune system. Cytarabine® is sold under the trade name Cytosar-U® by Pharmacia & Upjohn. It was FDA-approved for the treatment of certain leukemias in 1969, making it the first such approved marine-derived drug for use in cancer chemotherapy.

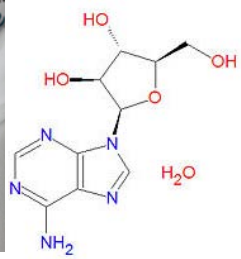
Clinical status of marine derived antitumor agents, their chemical class and mode of action

Compound Name	Structure	Chemical Class	Organism	Company	Status
Trabectedin (ET-743)		Alkaloid	Tunicate	PharmaMar	Approved
Eribulin Mesylate (E7389)		Macrolide	Sponge	Eisai Inc.	Phase III
Squalamine lactate		Amino-steroid	Shark	Genaera	Phase II
Plinabulin (NPI-2358)		Diketopipe-razine	Fungus	Nereus Phar-maceuticals	Phase II
Zalypsis		Alkaloid	Nudi-branch	PharmaMar	Phase II
LAF389		Amino acid	Sponge	Novartis	Phase I
KRN7000		-galactosyl ceramide	Sponge	Kirin	Phase I

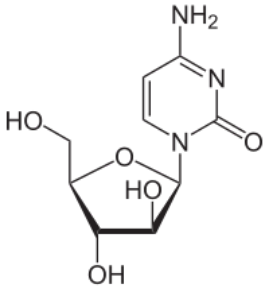
Compound Name	Structure	Chemical Class	Organism	Company	Status
Marizomib, Salinosporamide A; NPI-0052)		Beta-lactone-gamma lactam	Bacterium	Nereus Pharmaceuticals	Phase I
LY355703, CRYPTO 52		Cryptophycin	Cyano bacterium	-----	Preclinical

Diseases	Biomolecules/bioactive compounds	Marine source organisms
HIV	Cyclodidemniserinol trisulfate	Tunicate
	Lamellarin α-20-sulfate	Tunicate
Pain	Conotoxins	Gastropods
Cancer	Bryostatin	Bryozoan
	Didemnin-B	Tunicate
	Dolastatin 10	Sea hare
	Halichondrin B	Sponge
	Ecteinascidin 743	Tunicate
	Kahalaide F	Gastropod
	Aplidine	Tunicate
Asthma	Contignasterol	Sponge

(Modified after Kijjoa and Sawangwong 2004)



Vidarabine® (ARA-A)



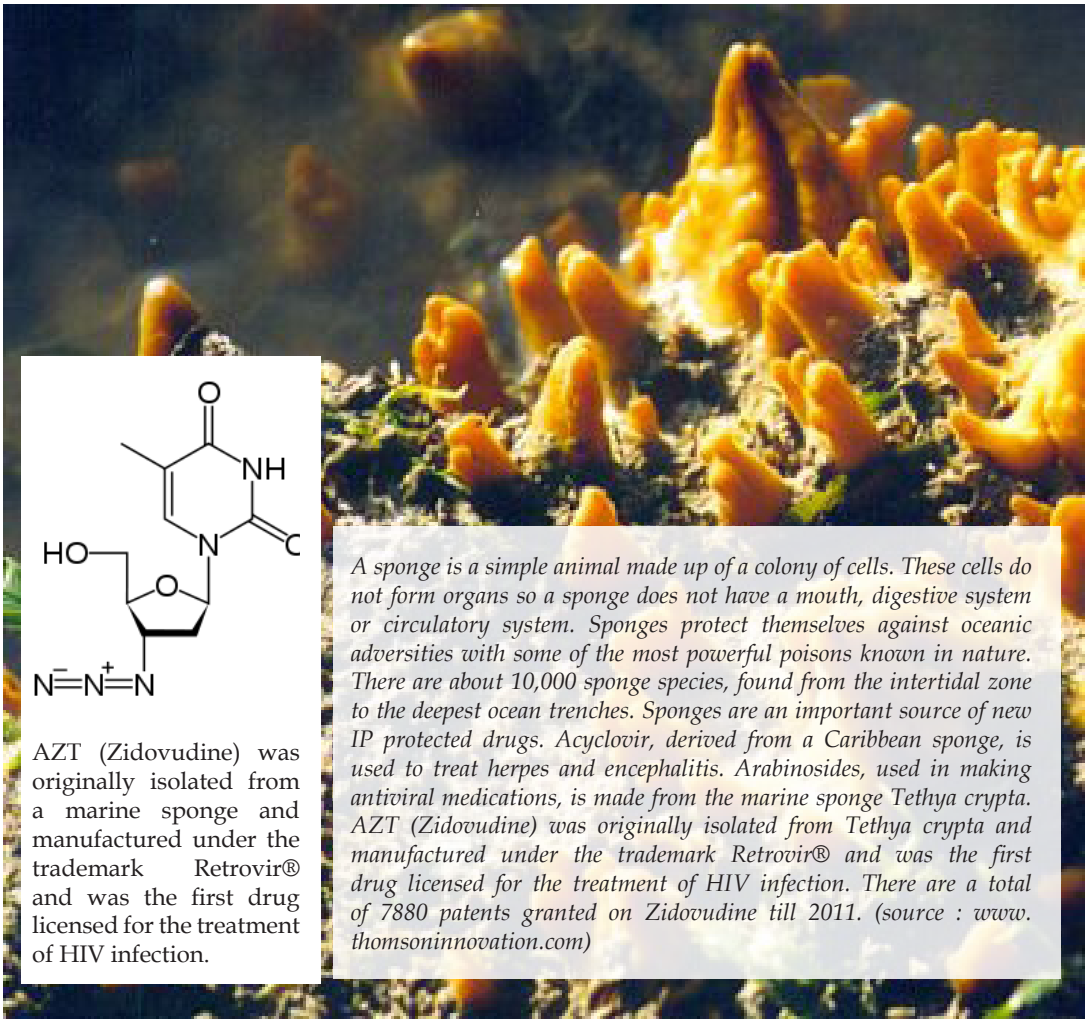
Cytarabine® (ARA-C)

Gracilaria corticata is a red alga that can be collected from many sea coasts around the world including India. Up till now, more than 2400 marine natural products have been isolated from seaweeds of subtropical and tropical populations (Manilal et al., 2009). G. corticata showed reasonable anticancer activity and it might be a good candidate for further investigations in order to develop a natural compound as an anticancer agent which can be used for the production of potential anticancer drug and novel pharmaceutical leads.

Seaweeds are the only source of production of phytochemicals such as alginic acid, agar-agar, carrageenan, iodine and the like, which are widely used in several industries involved in the manufacture of certain food materials, fertilizers and pharmaceuticals. Sargassum wightii (family Sargassaceae, order Fucales) is one of the major sources for the manufacture of alginic acid.

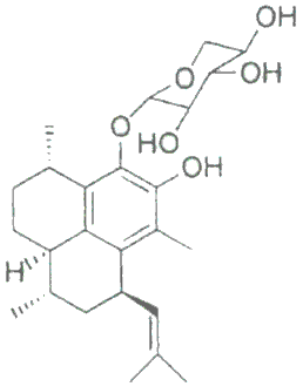
Azidothymidine (or Zidovudine, AZT) is an antiretroviral drug used for the treatment of HIV/AIDS based on a group of compounds (arabinosides) extracted from the sponge *Tethya crypta* more than 40 years ago. AZT was the first approved treatment for HIV, sold under the names Retrovir. AZT use was a major breakthrough in AIDS therapy in the 1990s that significantly altered the course of the illness. This success story frommarine ecosystem represents an annual market of about $50 million. AZT works by inhibiting the action of reverse transcriptase (Mitsuya *et al*., 1985; Yarchoan *et al*., 1986; Mitsuya *et al*., 1990).

Anti-inflammatory and analgesic pseudo pterosins isolated from a Caribbean marine gorgonian *(Pseudoterigorgia elisabethae)*, which led to the development of bioproducts now used in Estee Lauder skin care and cosmetics lines and currently worth $3-4 million a year. Pseudopterosins belong to a class of patented compounds known as tricyclic diterpene glycosides (Kijjoa and Sawangwong, 2004; Kohl and Kerr, 2003).



AZT (Zidovudine) was originally isolated from a marine sponge and manufactured under the trademark Retrovir® and was the first drug licensed for the treatment of HIV infection.

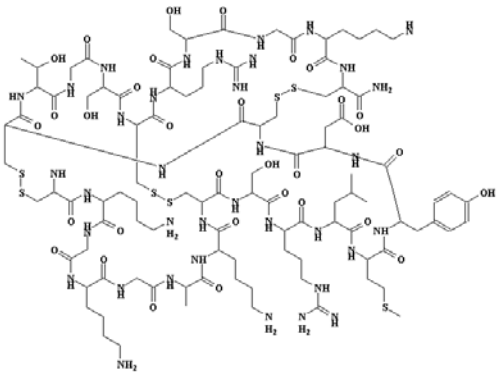
A sponge is a simple animal made up of a colony of cells. These cells do not form organs so a sponge does not have a mouth, digestive system or circulatory system. Sponges protect themselves against oceanic adversities with some of the most powerful poisons known in nature. There are about 10,000 sponge species, found from the intertidal zone to the deepest ocean trenches. Sponges are an important source of new IP protected drugs. Acyclovir, derived from a Caribbean sponge, is used to treat herpes and encephalitis. Arabinosides, used in making antiviral medications, is made from the marine sponge Tethya crypta. AZT (Zidovudine) was originally isolated from Tethya crypta and manufactured under the trademark Retrovir® and was the first drug licensed for the treatment of HIV infection. There are a total of 7880 patents granted on Zidovudine till 2011. (source : www.thomsoninnovation.com)



Pseudopterosins have been originally isolated from marine soft coral species called a sea whip **(***Pseudopterogorgia elisabethae***)**

Pseudopterosin bioproducts (Estee Lauder skin care & cosmetics) belong to tricyclic diterpene glycosides

Ziconotide (trade name Prialt®) is a synthetic form of a compound extracted from the venom of predatory tropical cone snails *(Conus* spp). The conotoxins from the various species of cone snails alone represent more than 100 patents and patent applications. In December 2004, Prialt® was approved by the FDA (approval was granted to Irish pharmaceutical company Elan Corporation to market its product for pain management) as a treatment for severe cases of chronic pain in patients who require intrathecal analgesia and conditions such as cancer and AIDS.



Cone snails are found in tropical seas, carnivorous mollusks known as cone snails sport venomous harpoons that can instantly paralyze small fish and other prey. The snails' venom contains hundreds of compounds, some of which chemists have used to create highly powerful, nonaddictive painkillers such as Ziconotide. Ziconotide (trade name Prialt®) is a synthetic form of a compound extracted from the venom of predatory tropical cone snails (Conus spp).

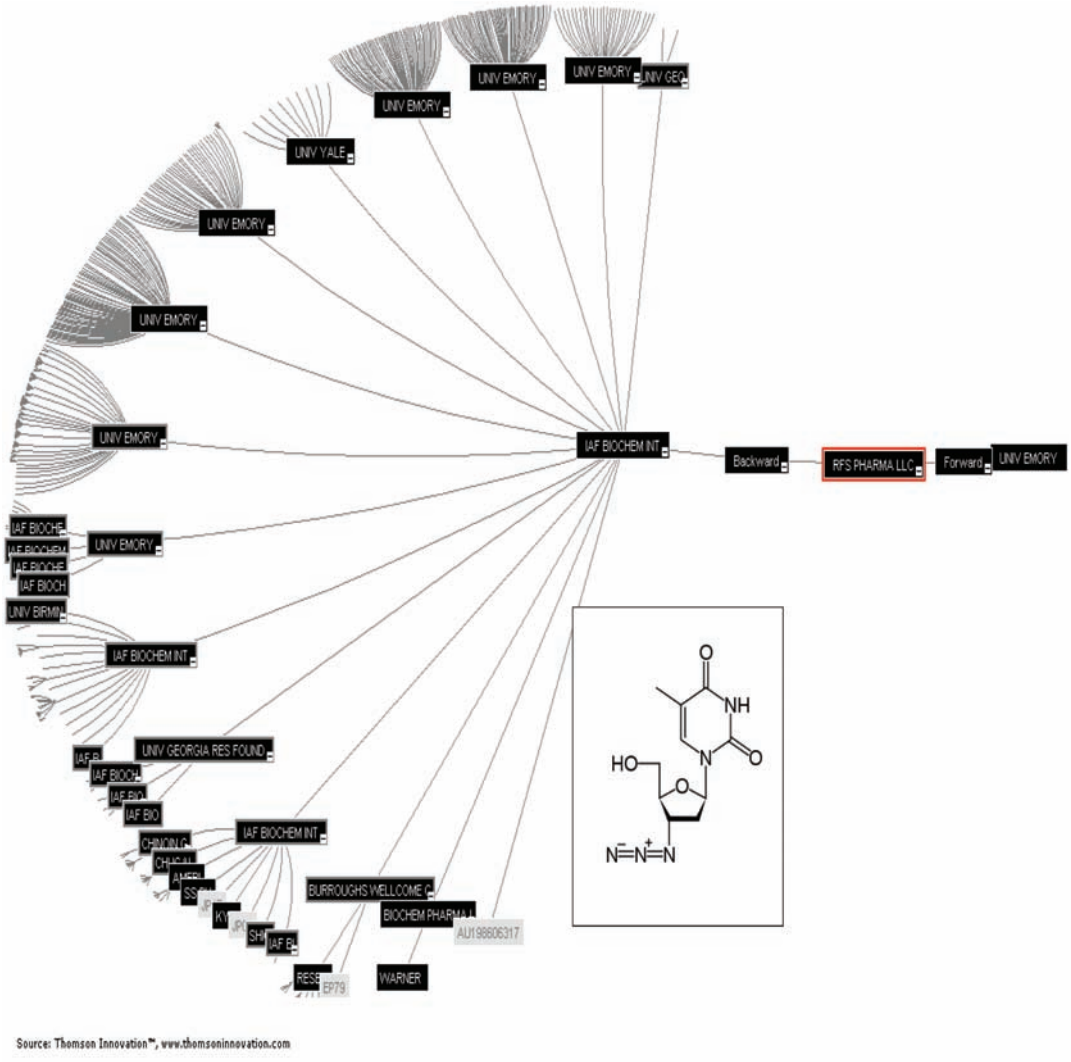
Patent Issues of Zidovudine (AZT)

Patents on Zidovudine have been the target of a plurality of controversies. Public Citizen filed a lawsuit during 1991, claiming patents related to AZT were invalid. Subsequently, Barr Laboraties and Novopharm Ltd. also challenged the patent, in part based on the assertion that National Cancer Institute (NCI) scientists Samuel Broder, Hiroaki Mitsuya, and Robert Yarchoan should have been named as inventors, and those two companies applied to the FDA to sell AZT as a generic drug. In response, Burroughs Wellcome Co. filed a lawsuit against the two companies. The United States Court of Appeals for the Federal Circuit ruled in 1992 in favor of Burroughs Wellcome, claiming that even though they had never tested it against HIV, they had conceived of it working before they sent it to the NCI scientists. In 2002, another lawsuit was filed over the patent by the AIDS Healthcare Foundation. However, the patent expired in 2005 (placing AZT in the public domain), allowing other drug companies to manufacture and market generic AZT without having to pay GlaxoSmithKline any royalties. The U.S. FDA has since approved four generic forms of AZT for sale in the U.S. In November 2009 GlaxoSmithKline formed a joint venture with Pfizer which combined the two companies' HIV assets in one company called ViiV Healthcare. This included the rights to Zidovudine (US Court of Appeals for the Federal Circuit. "Burroughs Wellcome Co. v. Barr Laboratories, 40 F. 3d 1223, *Fed. Cir.* 1994, University of Houston: Health Law & Policy Institute). There are a total of 7880 patents granted on Zidovudine till 2011 (www. thomsoninnovation.com). An example of the forward and backward citations of a patent related to Zidovudine has been cited in the next page (Publication number W02009045975A1, assignee/ applicant RFS Pharma LLC, publication date 2009-04-09, IPC A61K 31/70).

Citation Maps (A Case Study for Publ. No. WO2011161702A1)

Marine flora and fauna are rich with long-chain polyunsaturated fatty acids (PUFAs), which have vital pharmacological effects on human health. CMFRI is one of the institutes to develop polyunsaturated fatty acid concentrates from marine sources by chemical and lipase-catalyzed procedure

for use as a source for enriching larval for use as a source for enriching lerval feeds and broodstock diets of marine finfish and crustaceans and as nutraceutical supplements. There are several reported works on PUFAs and preparation of PUFA enriched supplements from marine flora and fauna. Forward and backward citations with respect to the patent publicatoin number WO2011/161702A1 are illustrated in the form various citation maps (Application number, IPC, US classification, assignee, application/publication dates, inventor and country) in the following pages.



First and second generation forward and backward patent citation map (Assignees are indicated here) with respect to the patent "Potent combinations of Zidovudine and drugs that select for the k65r mutation in the HIV polymerase" WO2009045975A1 (Inset: Zidovudine)

Process for separating polyunsaturated fatty acids from long chain unsaturated or less saturated fatty acids

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
29 December 2011 (29.12.2011)

PCT

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WO 2011/161702 A1

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C11C 3/10 (2006.01) *C11B 7/00* (2006.01)

(21) International Application Number:
PCT/IS2011/050011

(22) International Filing Date:
23 June 2011 (23.06.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
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(71) Applicant *(for all designated States except US)*: **EPAX AS** [NO/NO]; P.O. Box 2047, NO-6028 Aalesund (NO).

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(75) Inventors/Applicants *(for US only)*: **HARALDSSON, Gudmundur G.** [IS/IS]; Klyfjaseli 14, IS-109 Reykjavik (IS). **KRISTINSSON, Bjorn** [IS/IS]; Fjallalind 133, IS-201 Kopavogur (IS).

(74) Agent: **ARNASON FAKTOR**; Gudridarstig 2-4, IS-113 Reykjavik (IS).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

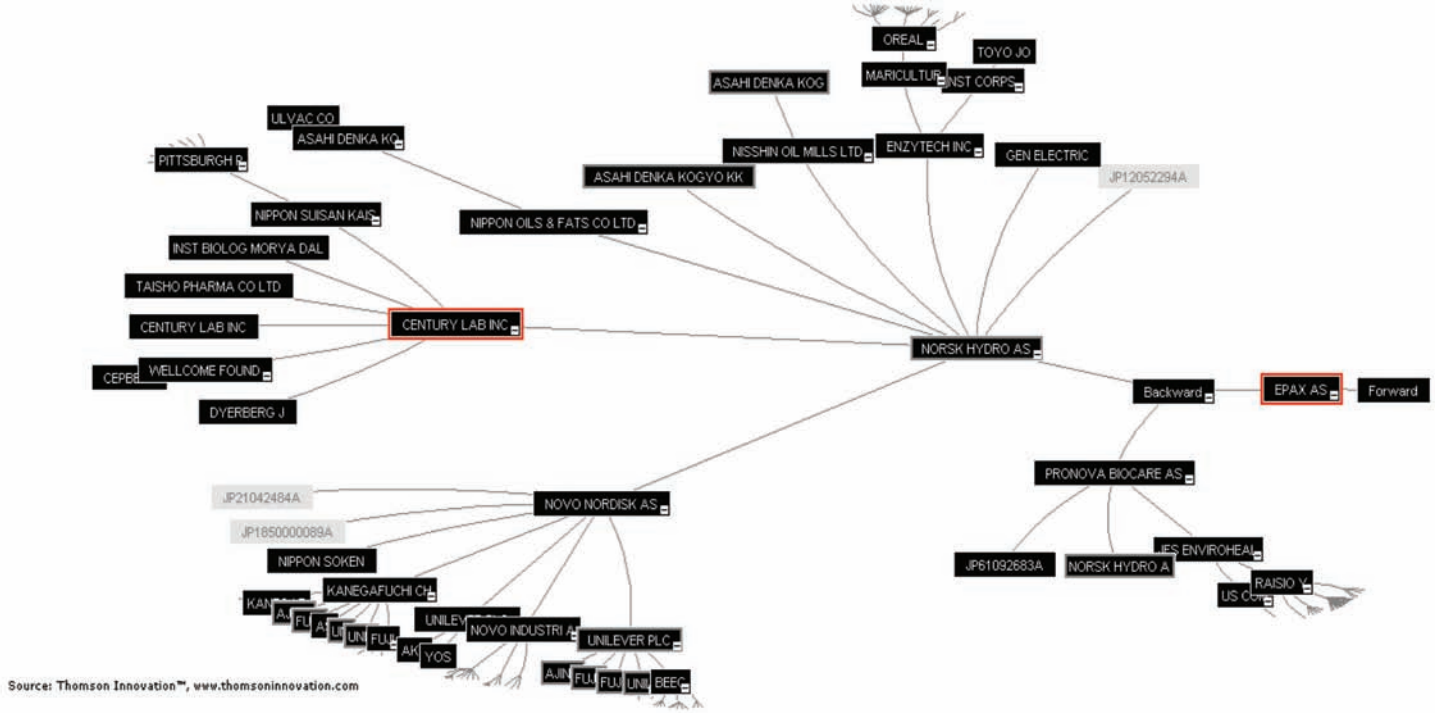
Declarations under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

Published:
— *with international search report (Art. 21(3))*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

WO 2011/161702 A1

(54) Title: PROCESS FOR SEPARATING POLYUNSATURATED FATTY ACIDS FROM LONG CHAIN UNSATURATED OR LESS SATURATED FATTY ACIDS

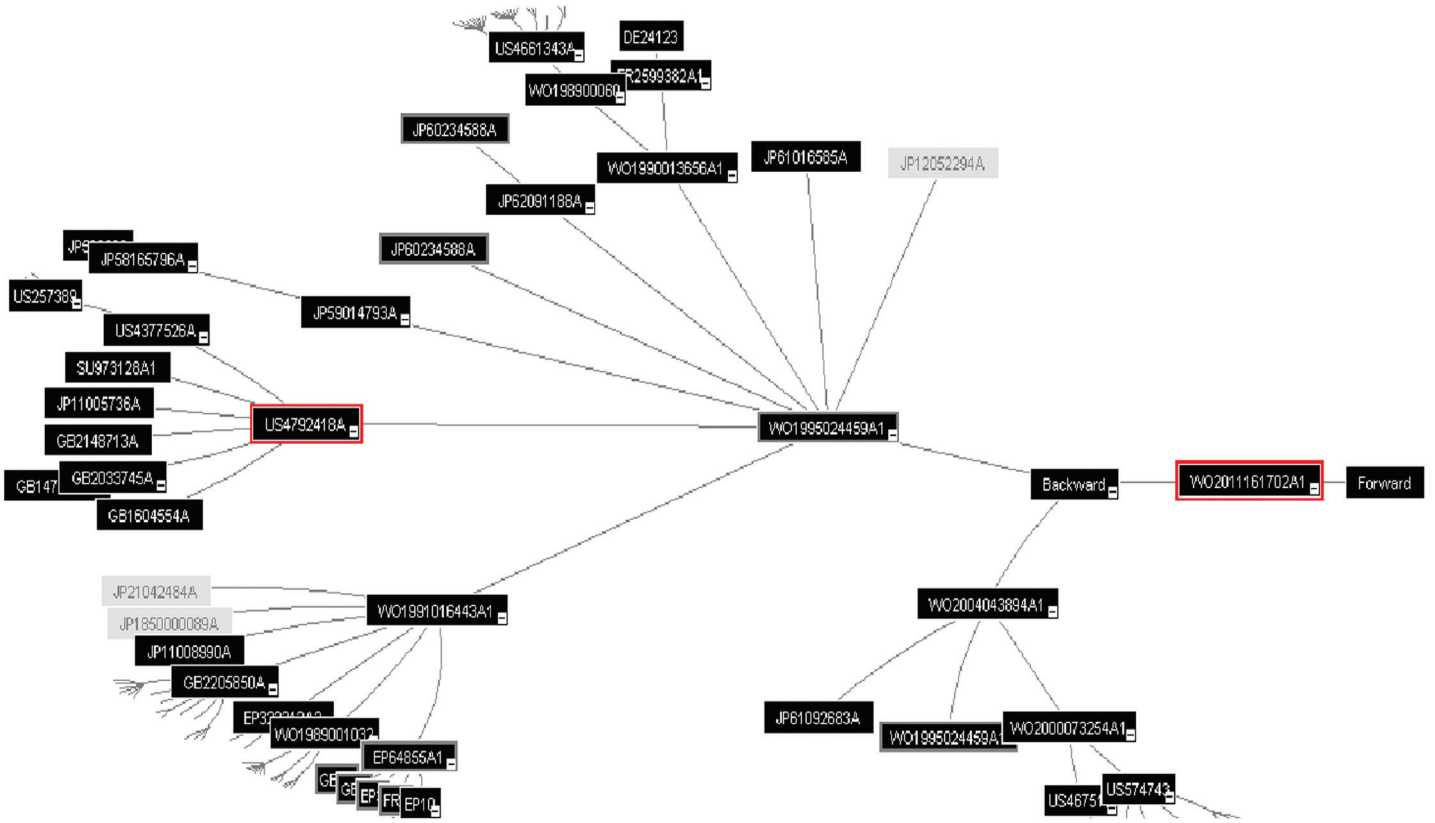
(57) Abstract: A process for separating polyunsaturated fatty acids (PUFAs) such as docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) from less saturated long chain fatty acids (LCFAs) in a lipid composition, wherein said PUFAs and LCFAs are present as (i) triglycerides, or (ii) free fatty acids or monoalkyl esters, by exchange of at least a portion of LCFAs with short and/or medium chain fatty acids (MCFAs). The process can suitably be employed on marine derived oil, marine oil 2 derived oil products and other sources of PUFAs, including PUFA-rich singe cell oils (SCOs), and oils from genetically modified orgamisms with a modified lipid metabolism. The inventive process is based on novel use of lipases and distillation techniques, selectively chemically modifying species in the substrate material such that the desired species and chemically similar species become sufficiently dissimilar to be separable. Thus PUFA can be effectively enriched from material such as 30 herring oil with low PUFA content and high contant of equal length monounsaturated fatty acids such as 20:1 and 22:1 fatty acids.



Forward and backward patent citation map (Assignee) with respect to the patent: WO2011161702A1, EPAX AS. There are no forward citations, whereas backward citation assignees are Norsk Hydro AS, which, in turn, cited several others (shown as tree) such as Gen Electric, Enzytechnic Inc., Nissin Oil Mills Ltd., Nippon Oils and Fats Co. Ltd., Century Lab., Novo Nordisk AS etc. The second and third generation backward citations are shown in the citation map.

Patent Citation Map (By Generation): WO2011161702A1

Publication Number	Assignee/ Applicant	Publication Date	Current IPC
WO2011161702A1	EPAX AS	2011-12-29	C11C 3/10

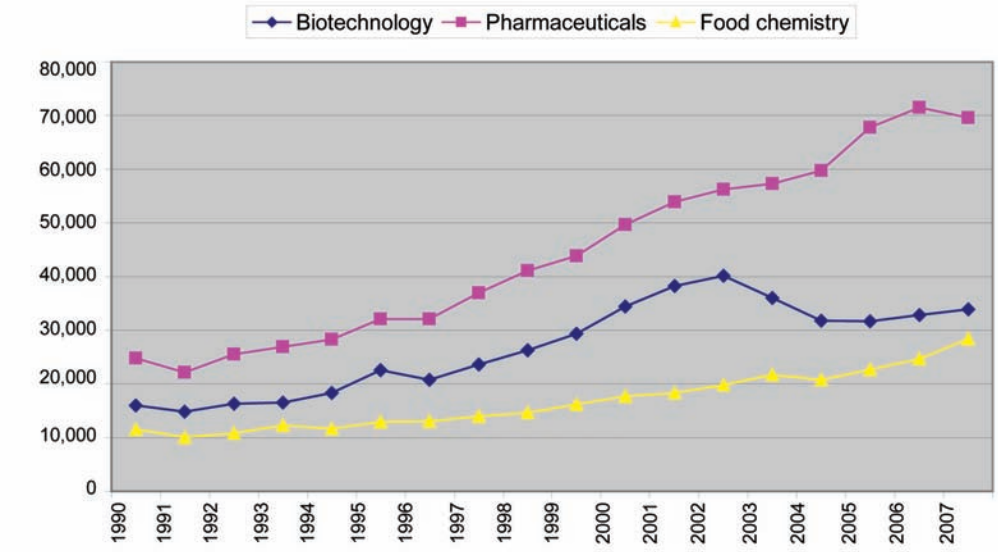


Second generation forward and backward patent citation map (Publication number) with respect to the patent: WO2011161702A1, EPAX AS (Base patent publication number: WO2011161702A1). The patent publication number referred to as WO2011161702A1 cited WO19995024459A1 (assignee Norsk Hydro AS), which, in turn, cited US4792418A (assignee Century Lab Inc.), JP59014793A (Nippon Oils and Fats Co. Ltd.), JP60234588A (Asahi Denka Kogyo KK), JP62091188A (Nissin Oil Mills Ltd.), WO1990013656A1 (Enzytechnic Inc.), JP61016585A (Gen Electric), and WO1991016443A1 (Novo Nordisk AS). These patents, in turn, cited several backward citations as shown in the citation map. It is to be noted that Japan has the largest share of foreign patent grants by the USPTO (40%, as recorded upto early 2010) revealing Japan's pre eminence as an innovator in recent years.

The Indian pharmaceutical industry is the world's second largest by volume and Indian biotech industry showed a 17% growth with revenues of Rs. 137 billion during 2009-10. Approximately one third of today's best selling drugs either are natural products or have been developed based on lead structures provided by nature. The development of genetic engineering and other biotechnological tools increased the use of biotechnologies in industrial processes.

Statistical estimates of the total number of patents filed in three leading areas revealed that about 70,000 patents have been filed in the area of pharmaceuticals (bioactive molecules) followed by biotechnological and food products (~30,000 patents during the year 2007). There appeared to be a tremendous increase in discovery of novel molecules from marine flora and fauna. During the year of 1990, about 25,000 pharmaceutically active molecules have been protected by patent laws, whereas the total number of patents in this area during 2007 has more than doubled. Marine ecosystem apparently contributes a major share of IP-protected technologies during recent years.

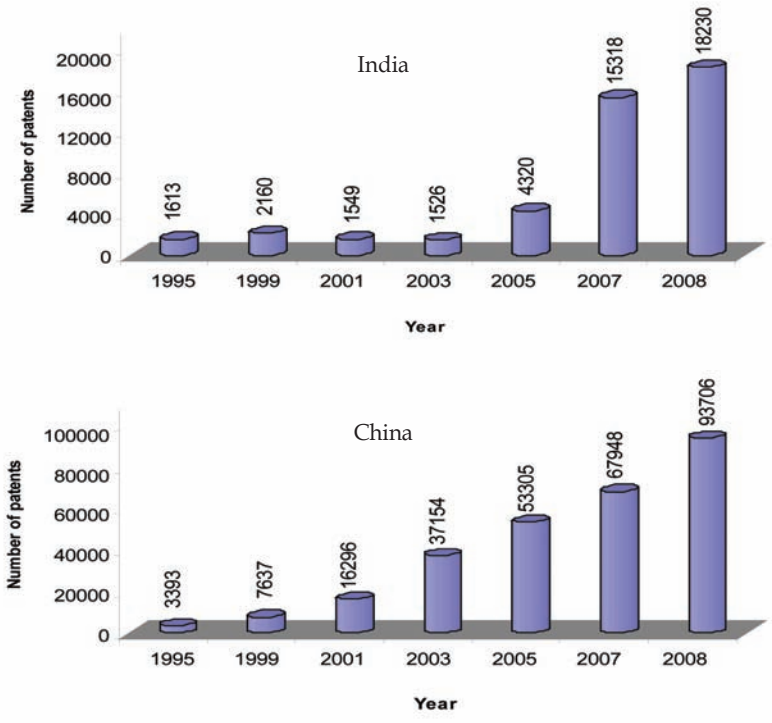
Natural products and related synthetic mimics or analogues are used to treat 87% of all categorized human diseases, and the discovery of novel IP protected agents is often used to better understand targets and pathways in disease processes. Compared with the study of terrestrial natural products, the study of marine natural products is still in its infancy. Rawat *et. al.* (2006) reported that over the past few decades, during which the study of IP protected marine natural products has begun in earnest, approximately 16,000 novel patent protected marine natural products have been discovered. These discoveries and related studies have been published in over 15,000 publications and protected by more than 300 patents (Donnelly 2010).



Patenting trend in Biotechnology, pharmaceuticals and food chemistry through 1990 to 2006 (Source: WIPO, 2007)

Most Commonly Used Indices of Innovation: Number of Patent Applications Filed Per Year in a Given Country

Japanese inventors had more than 2 million patents in force in 2010, over half a million more than the U.S. revealing Japan's preeminence as an innovator in recent years, even as the U.S. receives the most applications and Korea wins for per-capita, per-dollar GDP, and per-dollar R&D spend.



SOURCE: WIPO, Intellectual Property Statistics (http://www.wipo.int).

Japan has the largest share of foreign patent grants by the USPTO (40%, as recorded upto early 2010). The EU is second, with a 27% share. The Asia-8 group was in third place with 20%; its share nearly doubled from 2000 to 2010, largely because of rapid growth by South Korea and Taiwan. Chinese patenting activities in the U.S. remained insubstantial, as did those of Brazil, Russia, and India, in contrast to much higher activity of Chinese and other national patent offices. However, as compared to China the patents granted for favour of India remained insignificant (93706 patents by China as compared to 18230 by India during the year 2008).

Conclusions

Indian coastline and EEZ is gifted with an enormous resources of valuables hidden into the depths of sea, and can be explored to develop products with valuable patent protected nutraceutical, pharmaceutical and biomedical products for human health and well being. In doing so, our country can be the leader in this area if we efficiently harness the valuables for marine ecosystem and deliver efficient technologies from the sea, and to avoid other countries to intrude into our rich resources that happened earlier with turmeric, neem, and basmati rice. In this connection it is essential to develop knowledge in IP and patent protection of technologies developed by the inventor(s). An inventor can be deprived of his rightful share of recognition for his invention if malicious persons get hold of his product and promote it as their own. IP system comes to the rescue of the inventor in this situation. This will provide the true inventors with the due recognition to the ownership of an inventor over his/her innovative idea. The ultimate goals of any intellectual property system are safeguarding the rights of an inventor in his invention/ intellectual richness while benefiting the end users and society as a whole.

The IP system operates, as TRIPS agreement states, towards securing its objectives as follows: ".....protection and enforcement of intellectual property rights should contribute to technological innovation and to the transfer and dissemination of technology, for the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." This will encourage scientific research, new technology and industrial progress. The patent protection system must be worked out towards the benefit of all stakeholders-patentee, society, and above all, the nation.

Patents, therefore, play an important role as far as the commercial aspects of the product are concerned. The purpose of an invention is to protect and encourage fair competition in the field of technology so as to transform inventions or creations into real and productive forces at the earliest. A nation's market economy is dependant on the successful working of its patent system (Industrial Gases v Kamsup Industrial Gases PTC (Supp.) (2) 358. 368). The Patent Act contains general principles applicable to the working of all patented inventions. It is provided that "…in exercising powers concerning grant of compulsory licences, regard should *inter alia* be had to encourage innovations and to secure that inventions are worked in India on a commercial scale, and to the fullest extent reasonably practicable without undue delay, but to see that patent rights contribute to technological innovation, and to transfer and to disseminate technology for the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare and to ensure that the benefit of the patented invention is available at a reasonably affordable prices to the public and for grant of compulsory licences in respect of patents for the reasonable requirements of the public…" It is, therefore, obligatory for the patent holder/s or assignee/s to work out the patented invention towards commercialization for ensuring economic and social growth by providing an impetus to the advancement of science and technology towards the benefit of the society and mankind.

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CMFRI


UTTAMA
VARNA


Cadalmin
Green Mussel Extract
(GMe)


Cadalmin
Green Mussel Extract
(GMe)

APPENDICES

Annex - I

Recent Fee Structure for Filing and Maintaining Patents, Designs, and Trademarks

Patent fees*	
Charges and official fees	**INR Official fee**
Filing an application with provisional /complete specification with priority date	4000/-
For every additional priority date	4000/-
Charges for each additional claim in excess of 10 claims	800/-
Charges for each additional sheet of complete specifications in excess of 30 sheets	400/-
Prosecution	
Filing a request for substantive examination under section 11 (b)-non-expedited	10000/-
Filing a request for expedited examination	14000/-
Preparing and filing request for recordal of change of name, address, nationality or address for service	800/-
Filing request for recordal of assignment/ merger for pending application	2000/-
Filing request for recordal of assignment/ merger/license agreement for granted patent	4000/-
Request for amendment before grant of patent	2000/-
Request for amendment after grant of patent	4000/-
There are no official fees for reporting and replying to formal scrutiny report, reporting the first examination report/office action, preparing and filing response to the first examination report/office action, preparing and filing response to further office actions/examination reports, preparing and filing request with regard to details of foreign applications, filing details of search of corresponding applications, and hearing before the controller, and forwarding letter patent document	
Annuities	
3rd to 6th year	2000/-
7th to 10th year	6000/-
11th to 15th year	12000/-
16th to 20th year	20000/-
India Trademark ™ fee	
Official fees	**INR Official fee**
Trade mark searches in one class	
Filing application, checking, sending out filing receipt	3500/-

Additional class (including attending to advertisement, monitoring, paying fees, and forwarding registration certificate)	3500/-
Maintenance of TM registrations	
Recording an assignment of a registered trade mark (within 6 months)	5000/-
Additional mark included in the recordal	1000/-
Recording a change of name or address of the proprietor of a TM or registration	1000/-
Additional mark included in the recordable	500/-
Recording a registered user of a TM	5000/-
Additional mark included in the registered user agreement	3000/-
Renewal	5000/-
Design fees	
Charges and official fees	INR Official fee
Design and applications	
Filing a design application	1000/-
Extension of time for filing priority document (per month)	200/-
Extension of term/renewal	2000/-

International Applications (PCT)

Charges and official fees	**INR Official fee**
Filing PCT application including docketing and representation charges upto nationalization	8000/-
Basic Fee – Up to 30 pages of specification	53300/- (US$1184)
For each additional page over 30 pages	600/- (US$ 13)
Requesting for priority document	4000/-
Prosecuting the PCT application (considering and analyzing the search report issued by International searching authority and reporting the same and filing response)	2000/-
Suggesting a response to the written opinion and amendments under article 19 and 34	2000/-
Search Fee for EP	107000/- (US$ 2378)
Search fee for US	93600/- (US$ 2080)
Preparing and filing a demand	123200/- (EUR 1910)

* The Indian Patent Office charges a filing fee of Rs. 4000/- (~80 USD, Rs.1000/- (~20 USD) for individual applicants - 1 USD equals about Rs. 49/-) for each application, which is good for up to 30 pages and up to 10 claims. Any additional are charged @ Rs. 400 per page (~8 USD) and Rs. 800/- per claim (~16 USD) (@Rs.100 per page and Rs. 200/- per claim for individual applicants, whereas 1 USD equals about Rs. 49/-). Multiple dependent claims are not charged extra, unlike in the US.

Annex - II

Patent Offices in India

The Patent Office Branch, Mumbai	The Patent Office, Office of the Trademark Registry Bhoudhik Sampada Bhavan, Near Antop Hill Head Post Office, S.M. Road, Antop Hill, Mumbai-400037, India Phones Nos.: (022) 24137701 Fax : (022) 24120387 Email:- mumbai-patent@nic.in
The Patent Office Branch, Chennai	The Patent Office Intellectual Property Office Building Intellectual Property Rights Building, Industrial Estate Sidco Rmd Godown Area, G.S.T. Road, Guindy, Chennai-600032, India PhoneNos.: (044) 22322824-25, FAX: (044) 22322878 Email: chennai-patent@nic.in
The Patent Office Branch, New Delhi	The Patent Office Intellectual Property Office Building Bhoudhik Sampada Bhavan, Plot No. 32, Sector 14, Dwarka, New Delhi-110075, India Phone Nos.: (011) 28081922-25, FAX: (011) 28081920 Email: delhi-patent@nic.in
The Patent Office Kolkata (Head Office)	The Patent Office Intellectual Property Office Building Boudhik Sampada Bhawan CP-2 , Sector V, (Behind National Test House) Salt Lake City, Kolkata-700091, India Phone Nos.: (033) 23671943 - 46, (033) 23675092-93 FAX: (033) 23671988 Email:- kolkata-patent@nic.in Website: http://www.ipindia.nic.in

Technology Information Forecasting Assessment Council (TIFAC) is an autonomous organization under Department of Science & Technology, Government of India, is working in the field of Technology information, Forecasting for the last one decade. It has a Patent Facilitating Cell which is very active in patent related activities in India, also publishing a newsletter (Intellectual Property Rights Bulletin), advisory services, and case studies. The contact address is:-

Patent Facilitating Cell
Technology Information, Forecasting & Assessment Council
TIFAC, Technology Bhawan, New Mehrauli Road
New Delhi - 110 016, India
E-mail: tifac@nda.vsnl.net.in

For patent full text & search
Office of the Patent Information System
3rd Floor
Block 'C' CGO Complex,
Seminary Hills, Nagpur 440 006

Annex - III

Suggested Readings of Intellectual Property Rights

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