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Microbial Biopiracy in India: How to Fight Back?

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Some multinational pharmaceutical companies and other interested groups have unethically accessed rich microbial resources of India to obtain patents on them. Recently, the Patents (Amendment) Act, 2002 of India has included microorganism as a patentable invention in compliance with the TRIPS Agreement. The paper highlights the phenomenon of microbial biopiracy in India given the current scenario. Certain examples of piracy of various microorganisms from India by a few multinational pharmaceutical companies have been discussed which tries to prove the extent of activities of these companies. India will have to fight back this piracy of microbes immediately after meeting the international obligations. For standing up to this phenomenon, some sensible and systematic steps have been suggested. Prevention of biopiracy of microorganisms should be people's movement concerted with community, researchers, governmental agencies, NGOs, rather than haphazard initiatives.

With the advent of new biotechnology regime and restructuring of the patent laws by the member countries of WTO for discharging their obligations to comply with the TRIPS Agreement, microbial genetic resources are increasingly becoming important.

India is a mega biodiversity country having two biodiversity hotspots, namely the Western Ghats and the Eastern Himalayas which are included amongst the top eight most important hotspots in the world[1], 10 biogeographic regions, two major realms called the palaearctic and the Indo-Malayan, and three biomass, namely, the tropical humid forests, tropical dry/deciduous forests and the warm deserts and the semi-deserts[2]. From the patentability point of view the microorganisms available in the soil, river water, and marine water are of much importance. India has 850 species of bacteria, 14,500 species of fungi, 6,500 species of algae, 2000 species of lichens, 2,850 species of bryophytes, and 1100 species of pteridophytes[3]. Displacement of these microbial resources without the knowledge of the donor country resulted in the unprotected flow of knowledge from gene rich India to the capital rich west, and a protected flow in the reverse direction.

Definitions

What are microorganisms? It is very difficult to come to a consensus on a sin-

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gle definition. Neither the word microorganism is defined nor any parameter is specified in the TRIPS Agreement, which has created a lot of confusion regarding the patentability of microorganism. Microorganisms may include bacteria, viruses, viriods, eukaryotic single-cell and multicellular microorganisms like yeast, protozoa, fungi, moulds and algae and cultured plant and animal cells. But this does not cover all the aspects of complex biotechnological inventions. Microorganism may be defined as any biological material that is self-replicable or replicable via a host organism and includes subcellular material like genes, gene sequences, and plasmids, etc.[4] This definition is also not flawless.

Biological diversity or biodiversity has been defined in the chapter I section 2(b) definitions of Biodiversity Act, 2002 (No. 93 of 2002) of India as "the variability among living organisms from all sources and the ecological complexes of which they are part and includes diversity with species or between species and of ecosystems." Section 2(c) of this Act includes the term 'biological resources' meaning plants, animals and microorganisms or parts thereof, their genetic material and by-products with actual or potential use or value but does not include human genetic material[5].

Extent of Microbial Piracy: An Example

In 1969, a microbiologist working for Sandoz, a large Swiss company, collected soil samples while on vacation in the Hardangervidda Mountains of Norway. He took samples with him back to his laboratory in Basel, Switzerland. One of those samples contained a biochemical 'Cyclosporin A' which later became the active ingredient in the blockbuster drug Sandimunn Neoral, that is used by the patients that have undergone organ transplant operations. In 1996, Sandoz merged with Ciba Geigy to form Novarties, and in the following year medicines from Norwegian fungus reportedly earned Novarties US$1.2 billion in gross revenue. However, the collection and use of the soil samples described above was not illegal, because at that time there were no Norwegian laws requiring access authorization or benefit sharing provisions for this type of activity. A decade after the Sandoz microbiologist collected his sample, Norwegian government converted that mountain region into a national park, but even this action failed to establish laws governing bioprospecting[6].

There is a distinct difference between biopiracy and bioprospecting. The term 'biopiracy' describes the unauthorized and uncompensated taking and use of biological resources. In contrast, bioprospecting refers to the search for valuable active chemical compounds in nature, and involves accessing natural resources through legal means, securing prior informed consent from the custodians of the relevant natural resources and promoting equitable benefit sharing agreements with appropriate parties. Biopiracy deprives not only the custodians of biological resources but also the country concerned**.**

The Life Industry

The life industries use, buy, sell, patent

and control an ever-growing market share of bio-industrial products. With the advent of genetic engineering, the gene giants are staking far-reaching claims of ownership over a vast array of microorganisms and microbiological processes. The power of patents is giving these companies the legal right to determine the ownership and its price. This has serious implications for the future of world food security and for conservation of biogenetic resources.

Some of the important foreign companies active in India for collection of microorganisms and their screening are given in Table 1 (ref. 7).

Biopiracy of Microorganisms: Some Examples from India

A list of some microbial piracy cases from India given in Table 2, is not an exhaustive one but is rather indicative in nature. The following biomaterial was collected from the donor country (India)

Table 1—Foreign companies active in India for collection of microorganisms

Companies	Active since	Collectors	Capacity	Natural Product focus	Therapeutic groups
Abbott Labs	1950	Independent	20-50 primary screens	Microbes, Plants	Anti-infective, Cardiovascular
Bristol-Myers Squibb	Company established	Independent	Not available	Fungi, Microbes, Marine Microbes	Anti-infective, Antiviral, Cancer
Ciba-Geigy	1989 (marine), 1992 (tropical plants)	Harbor branch Ocean Inst, Independent	4000 samples tested (1991)	Microbes, Plants	Anti-allergy, Respiratory, Cancer
Eli Lilly	1960	Independent researcher	Not available	Algae, Plants	Anti-viral, Diabetes, Skeletal diseases
Glaxo Group Research	1988	Univ. of Illinois, Biotics Ltd	Not available	Fungi, Microbes	Cancer, Anti-infective, Cardiovascular
Merck & Co, Inc	1991	INBIO, MYCO search	Not available	Fungi, Marine and Land Microbes	Cancer, Prostate, Bone diseases, Anti-viral
Monsanto	1989	Missouri Botanical Garden	9000 samples per year	Microbes, Plants	Anti-inflammatory, Cardiovascular
Pfizer	Not available	NY Botanical Garden Independent	Not available	Microbes, Spider Venom, Plants	Immunoscience, Gastrointestinal, Cardiovascular
Rhone-Poulenc Rorer	1991	Independent	100 samples per year	Microbes, Marine Plants	AIDS, Cancer, Respiratory
Smith Kline Beecham	1987	Scripps Inst of Ocean, In – house collectors	2-3000 samples per year	Microbes, Plants, Marine Microbes	CNS, Anti-inflammatory

Table 2—Microbial piracy cases from India

ATCC*	Depositor	Material	Purpose	US Patent
31466	Pfizer	Soil bacteria	Antibiotic compound	4,195,079
31121	Lepetit Labs	Soil bacteria	Teichoplanins	4,239,751
31430	Bristol –Myers	Soil bacteria	Antibiotics	4,250,170
21828	Bristol –Myers	Soil bacteria	Antibiotics	3,880,994
31203	Bristol –Myers	Soil bacteria	Capreomycin	4,287,182
31724	Bristol –Myers	Soil bacteria	Nocardicins	4,320,19
31086	Bristol –Myers	Soil bacteria	Sorbistin	4,012,576
53712	Bristol –Myers	Soil bacteria	Anti-fungal	4,956,374
31217	Bristol –Myers	Soil bacteria	Apramycin, Nebramycin, Tobramycin	4,032,404
31219	Bristol –Myers	Soil bacteria	Apramycin, Nebramycin, Tobramycin	4,032,404
39012	Pfizer	Soil bacteria	CP-56, 063 and CP-56, 064	4,450,237
13382	Lederle Labs	Soil bacteria	Nucleocidin	2,914,525
53527	Merck	Soil bacteria	Virginiamycin and its analogs	4,476,111
20927	Merck	Soil fungus	Pyranyl ester	4,952,604

*American Type Culture Collection in Rockville, Maryland, USA — An International Depositary Authority (IDA)
Source: ETC Group, Canada (Earlier RAFI, Canada)

before the UN Convention on Biodiversity (1992) came into force. Thus the material is the property of the depositor and not of the donor country. If intellectual property claims are made against any of this material, royalties will be paid solely to the depositor.[8]

Impact of Microbial Piracy

Biochemical information contained in wild plants, animals and microorganisms is the integral part of the life of indigenous people. Thus biopiracy must be considered as encroaching on their biocultural democracy and denial of the sovereign right of a nation at large.

Another inevitable offshoot of microbial biopiracy is genetic erosion. Patents and other forms of IP protection narrow the genetic base of a nation.

Microbes having harmful traits like *Bacillus anthracis* may be used against the community as a biochemical weapon. On the other hand, many beneficial microbes come back to the community in a legally protected form through patents.

Patentability of Microorganisms

Apart from the basic criteria needed for a patent, i.e. novelty, non-obviousness and industrial application, patenting of microorganisms require deposition of microorganisms in a recognized depositary authority, as mentioned in the specification, by the inventor. India has joined as 53rd member (on 17th December 2001)

of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent procedure. Recently, India has passed the Patents (Amendment) Act, 2002 (Presidential Assent on 25th June 2002) in compliance with the TRIPS Agreement. This act made microorganisms patentable in India.[9] Among the 34 International Depositary Authorities (IDA) worldwide, the Institute of Microbial Technology (IMTech), Chandigarh, is the sole representative from India.

Legal Perspectives

As a signatory to WTO, India is bound to meet the obligation of the TRIPS Agreement. Item 3(b) of article 27 of the Agreement says microorganisms, and non-biological and microbiological processes have to be eligible for patents.

India is also the member of UN Convention on Biodiversity (CBD). CBD asserts (Article 15–Article 19) the sovereign rights of nations over their national resources, and their right to determine access according to national legislation with the aim to facilitate the sustainable use of resources, promoting access and their common use. It notes that access to genetic resources takes place on mutually-agreed terms, which provide fair and equitable sharing of the results of R & D and the benefits of commercialization and utilization[10].

National Legislation

To comply with the CBD, India has passed its own Biodiversity Act, 2002 (No. 93 of 2002). Clause 19 of this Act mentions: all foreigners/non-residents/a body corporate or association or organization not registered or incorporated in India or any non-resident participation in share capital or management of these organizations (sub-section 2 of section 3) will require prior approval (through prescribed application form and fees) from the National Biodiversity Authority (NBA) for doing any research, commercial utilization, bio-survey, bio-utilization and transfer of research results relating to any biological material occurring in India. Clause 20 reveals that the above mentioned categories of people will not be eligible to transfer of biological resources or knowledge unless NBA has given the prior approval to that effect.

The passing of the Patents (Amendment) Bill, 2002, by both Houses of Parliament is one more step towards complete compliance with the TRIPS Agreement. India has time until 1 January 2005 to comply further with the Agreement. The scope of patentable inventions has been widened to include microorganisms. The duration of the term of patent has been extended to 20 years for all process and product patents as are patentable under the existing Act (Section 53) as well as those included in the present Act. According to the earlier Patents (Amendment) Act, 2001, only new microorganisms could be considered as invention. This amendment envisages extension of the scope of the 'chemical process' to include biochemical, biotechnological, and microbiological processes.

Section 10 (contents of specification) of the Patents Act, 1970, as amended by the Patents (Amendment) Act, 2002, insists on the complete and comprehensive

disclosure of the contents of the invention in the form of specifications of the patent application. The proposed amendment also intends to enhance its scope to cover the manner of disclosure of the contents of the inventions relating to biotechnological products and processes involving microorganisms. The new law [section 10(40)(d) (ii)] mandates deposit of biological material (microorganisms) with an approved depositary institution and incorporation of its specifications, including the name and address of the depositary institution, number and date of deposit and detailed characteristics and source and origin of the biological material (microorganisms) should be made on or before the date of the patent application in India. Also, section 25 (opposition to grant of patent) as amended allows for opposition to be filed on the ground that "the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention." Public access to the material from the depositary institutions permitted only after the date of patent application in India or after the date of the priority application and /or after date of publication of the application in the Gazette under this section.

Question of Ownership

The loss of biogenetic resources including microorganisms is partially explained by the lack of clear definition of 'microorganisms' and poorly implemented or enforced property system. The property system is a central institutional means for arranging socially the management and utilization of land and biogenetic resources. Property right regimes are human creations "whose purpose is to manage people in their use of environmental resources."[11] They consist of rules that determine relations between persons with respect to property objects. The owner of a certain object is the person who has the greatest recognized interest in the object itself or in the benefits it generates[12].

One basic feature of ownership is the exclusion of non-owners. For non-owners the access to a thing is closed or strictly limited on such conditions as the will of the owner. Resources that exist outside legitimate or well-enforced property claims are called 'open access resources' and no one exercises exclusive control over them and in principle no one is excluded from their use. Often it is the case that when genetic resources are conceived of as a common heritage of mankind. They can be used for research and development of commercial applications without restriction. But when an abstract object, such as genetic information, is patented it changes the whole nature of this particular resource base: it becomes an exclusive commodity. The idea of an object being freely accessible and thus outside allocation and rules of use has to be distinguished from its being unownable, i.e. unsuitable for being a property object[13].

Some Legitimate Questions

The CBD asserts that the right to biological resources is a sovereign issue and at the same time CBD details how the nation should, by national legislation,

provide for access to genetic resources, which is highly contradictory.

Neither CBD nor the TRIPS Agreement has defined the term 'microorganisms'. CBD does not provide the exact mechanism of benefit of sharing and the mandatory requirements of the agreement between the parties. In article 8(j), the convention emphasizes the requirement of "prior informed consent" but it does not specify it. It says nothing about the extent of information that should be provided by the multinationals to the community. Whether the community has complete knowledge about the possible commercial benefit that may be derived from the intellectual property (IP) protection of the multinationals is not clear from the text of the convention. CBD does not provide any right to the nation or people regarding biogenetic resources exchanged before 1992.

The TRIPS Agreement does not recognize traditional knowledge while most of the biological resources are parts of traditional knowledge. It does not require mentioning of the source of biological material and associated traditional knowledge and any commitment for fair and equitable sharing of benefits with the country of origin or holders of traditional knowledge.

Regarding the disclosure of origin of genetic resources to counter biopiracy many queries are still unanswered in CBD and all the relevant legislations like Biodiversity Act, 2002, of India and in the Patents (Amendment) Act 2001 and 2002, particularly, in case of *ex situ* collection of samples. In section 7 of the Biodiversity Act, 2002, local people, communities, *vaids* and *hakims* are allowed to collect and practise indigenous medicine and this provision can be misused by the multinationals for *in situ* collection of the sample. Section 21 of this Act says about equitable benefit sharing but it does not specify the amount and extent of information that should be received by the communities. It is even silent about whether the communities have been provided with the proper knowledge about the commercialization of the resources or not. Neither Biodiversity Act, 2002, nor the Patents (Amendment) Act, 2002, has provided any mechanism or tool to verify the source/origin of the genetic resources as mentioned by the inventors in the specification. There are many more loopholes in Biodiversity Act, 2002, and in the Patents (Amendment) Act, 2002, which need to be addressed immediately.

Recommendations

Standing up to microbial biopiracy cannot be done by a single effort rather it should be a combination of efforts. No combination is final, but is subject to change, sensibly from time to time, as situation demands. The following combination of concerted efforts or initiatives can be a good start towards this**.**

Clear Definition

Microorganisms must be defined by all the concerned national and international legislations in order to avoid confusion. Recently, in the Patents (Amendment) Act, 2002, India has included microorganisms as patentable inventions but has not defined it. As a signatory to the

TRIPS Agreement India is bound to comply with it. But no country is prevented from defining the term microorganisms. India must take that advantage to define the term as soon as possible in future amendment of the Patent Act. This is the first step to combat microbial biopiracy effectively.

Inventorization

It is not only sufficient to observe, identify and classify microorganisms present in soil, river and marine environment but also it is essential to record their physical and chemical properties that may get IP protection. This can be done in the following steps:

(a) Isolation

First isolate the various microorganisms from their environment. Here *in situ* collection is highly recommended and the knowledge of the local people/community must be taken into account.

(b) Identification

Identification can be done by DNA finger printing technique. This is the most important step, which requires especially skilled manpower.

All living organisms have mobile elements in their genomes. That is a general feature. However, the properties of mobile elements and their number strongly vary from one species to another. These are called 'minisatellite' and 'microsatellite sequences ' (ms, mcs). They are represented by several dozen to several hundred copies spread throughout the genome.

The easiest way to visualize the variability among individuals is as follows: DNA isolated from microorganisms is cut by one of the restriction endonucleases, i.e. the enzymes cutting DNA only at specific sites containing a certain sequence of 4-8 base pairs long. As a rule, restriction endonuclease is used which cuts DNA in many different places but not within the minisatellite sequence leaving the internal repeats intact. As a result, the whole minisatellite sequence is not cut whereas the flanking sequences are cut not far from the minisatellite boundaries. After electrophoric separation of DNA fragments and hybridization with a minisatellite probe, one can see the pattern of size distribution of individual minisatellite copies. It is a very good method for individual identification. Thus, the distribution of mini- and microsatellite bands is a sort of genetic portrait of a given organism. Therefore, the method is called 'DNA fingerprinting' and the picture of distribution of the bands, a DNA fingerprint.

This DNA sequence, designated as the M13 minisatellite (abbriviation-M13 ms) is present in almost all the microorganisms including bacteria, fungi, etc analysis of M13 ms helps solving many problems. These include individual identification, identification of cell lines and bacterial strains, epidemiological analysis, etc. Using blot–hybridization with M13 ms DNA, one can distinguish between pathogenic and non-pathogenic strains of bacteria[14]. The method was also successfully used for the identification of some phytopathogenic fungus[15].

This identification and classification in a hierarchical way is not only important from biological point of view but also

very important in the perspective of intellectual property rights (IPR). It provides a simple strategy for exploring effectively and efficiently the possible benefits and harmful consequences of the microbes. The microbial diversity is so great, and its beneficial and harmful properties so imperfectly known, that an exploration of 'closest known relatives' rather than random search is by far the more economical and effective strategy.

After identification, microorganisms or its parts thereof should be deposited in any recognized depositary or in the National Gene Bank or any recognized institution where the facility to preserve the microorganisms exist.

(c) The Final Step

Thus, all the collected information after identification of the microorganisms must be systematically mentioned in the inventory. Parameters and fields of description in the inventory should fulfill the IPR objective. Following fields can be set to make the inventory:

(i) Geographical location (up to village level), (ii) Community/local use (if any), (iii) Bioactive substances (if any), (iv) Beneficial properties (if any), (v) Harmful properties (if any), (vi) Classification up to order level (if possible), and (vii) Close relatives (if any).

Thus, mechanism of making inventory is a multi-step phenomenon. It is recommended that the initiative should start from the grass root level where it actually originates. Participation of NGOs is welcome for creating mass awareness regarding equitable benefit sharing. Autonomous central agencies like the National Innovative Foundation (recently established), TIFAC (Technology Information, Forecasting And Assessment Council) and similar state agencies can also help in this regard significantly. A link should be established in between the community making this inventory and the National Gene Bank or any concerned laboratory where the identification will be done. Central and state governments should fund this initiative as an important investment for the future.

Change in Legislation

The CBD must clear its stand to clarify the term 'sovereign right'. If a nation has to provide the access of its genetic resources to the interested parties then it must have a right to refuse the access when the need arises.

Indian Patents Act must incorporate the clause of access refusal to protect our biogenetic resources. India must recognize the community inventory as legally authentic document in the perspective of equitable benefit sharing and the patent opposition or revocation. The Patents (Amendment) Act, 2002, must include a mechanism or tool by which it can be ascertained that disclosure of the origin is not a fabricated one. Violation of Sections 7 and 20 of Biodiversity Act, 2002, and section 10 of the Patents (Amendment) Act, 2002, must be considered as criminal offence leading to non-bailable criminal punishment. Though the Patents (Amendment) Act, 2002, excluded traditional knowledge from patentability but it must be reconsidered in future. Finally, India must establish a dialogue regarding the TRIPS Agreement in the international

platform keeping the country's interest in mind.

Sanction

Sanctions must be applied wherever it is found that the patentee has failed to disclose the source or where he has sought to deliberately mislead about the source. A system should be established whereby patent offices examining patent applications which identify the geographical source of genetic resources or traditional knowledge pass on that information, either to that country concerned, or to WIPO which may act as a depositary for patent-related information on alleged "biopiracy". Through these measures it will be possible to monitor more closely the use and misuse of genetic resources[16].

Blacklisting a Biopirate

Those who evade access restrictions are branded as 'biopirates' and will suffer from bad reputation. They will find it increasingly difficult to find doors open for further research. A company that is associated with biopiracy may end up with weak patents, be exposed to equitable claims for profit – sharing, lose sources of supply, face the prospect of consumer and government boycotts, barriers to importation of biotechnology products, and other loss of market share, and may face financial penalties.

Conservation-based Bioprospecting Framework for Researchers

Promotion of conservation based bioprospecting framework can reduce the microbial biopiracy significantly and valuable research can be increased. This is specially true since many researchers prefer to work in areas that facilitate cooperative and mutually beneficial agreements, which strengthen the long-term viability of research investments. In the process the resource custodian's ability to preserve and protect the biological resources essential to the researchers can be improved.

Community-based Framework

Ultimately, it is better for communities/local people to begin taking measures to develop their own conservation based bioprospecting frameworks now, and pursue partnership with the research community soon. This is quite evidenced from Norway's tale of losing US$1.2 billion. This framework must be incorporated with the making of community inventory programme.

IPR Literacy and Training

In India, IPR literacy among the so-called educated class is in such an abysmal state that here even many scientists are not aware about the basic criteria for granting of a patent. On the other hand, some communities and local people were found to be well acquainted with biopiracy and its impact on biodiversity. This gives insight to the actual problem. India needs IPR-educated scientists and mass awareness. Proper training, which is relevant to the concerned, can solve this problem. Knowledge of natural sciences/ technology/ engineering/social sciences at the tertiary level should be the prerequisite for training in various aspects of IPR. Initiatives can be taken by the Central and state governments and NGOs.

In the conclusion it can be said that India must take the advantage of being a mega biodiversity country and negotiate regarding the TRIPS Agreement in the international platform. India must take the countrywide consensus before this negotiation and regarding further amendment of the Patents Act. Research must begin immediately to explore the cases relating to microorganisms, which has been patented after 1992 to recover the financial loss incurred by the nation. In fact, combating microbial biopiracy cannot be a single person's work, but it should be based on the coordinated initiatives of community, researchers, governmental agencies and above all common people.

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