Sri Lanka a victim of biopiracy

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Sri Lankan microbe covered in U.S. patent

The unauthorized use, export and commercial exploitation of biological resources of a country and the associated knowledge is known as biopiracy. In addition to the often encountered cases of using known medicinal plants and associated traditional knowledge base to develop new phermaceutical compounds, there is increased exploitation of micro-organisms from the biodiversity rich countries and regions to identify new, useful compounds. Once a promising substance is found and isolated, a patent is applied for, to get a monopoly over it, before venturing on to make a product on a commercial scale. A number of compounds isolated from micro-organisms found in Asia have been patented in the United States of America. A microbe from Sri Lanka is yet another addition to the list of pirated organisms.

This is the patent No. U.S. 5,541,181, issued on 30th of July 1996 by the U.S. Patent and Trademark Office (USPTO) to the Bristol-Myers Squibb Company in New Jersey U.S.A., titled 'compound produced by a strain of Micromonospora'. The two inventors mentioned are Japanese nationals Hiroaki Ohkuma and Seikichi Kobaru from Japan. The microbe is identified as Micromonospora sp. M990-6, said to have been solated from a soil sample collected from Colombo, Sri Lanka. A sample of this microbe had been deposited in the America Type Culture Collection under the Accession number ATCC-55378 on 17.11.1992. The new compound isolated from it is given the name BU4664L. The application for the patent had been forwarded on 20.05.1994.

These preliminary information itself poses several questions.

** Whether the locality given in the patent (Colombo) is true. Microbe of this group are usually found on soil with rotting leaf litter in wet forests.*

** Whether these two Japanese nationals came to Sri Lanka to gather samples or brought it from yet another source.*

** If they got samples through a collector/ collaborator, who that source is and whether any Sri Lankan nationals are involved*

** When was the samples collected*

** How were they exported*

** Who exported them*

** Are there any more microbes taken out of Sri Lanka which are yet unknown and awaiting patents*

** Whether the two inventors are employees of Bristol Myers or whether the company brought the rights from them.*

It is a common practice of some companies to buy strains of microbes once it is known to be of same promise and some researchers themselves canvass companies to sell their findings. It is also possible that these two were independent contractors working on behalf of the company. The locality where the microbe is said to have been found (type locality) may not be the true locality, as the necessary conditions for such microbes to thrive does not exist in the city. In scientific papers, it is essential to give the correct locality. In a patent like this one, it is not necessary to give such correct information and can give the locality in a very vague manner. The reason for not disclosing true locality in a patent document may be two fold. The keeping of the type locality secret may help the collector if it looks promising as it could well yield other microbes that may bring more profit. If such a locality becomes known, others will also start collecting there. Secondly, if the collector is a scientist, he may have withheld this information till it is scientifically described and named as a new species.

According to the patent, the filaments or mycelia of this microbe varies in colour according to the medium on which it is grown. It is said to vary from yellowish — white, bright yellow, bright orange, yellowish — brown, brownish — olive, dark grey to black. For instance, the mycelie are bright orange when grown on an oatmeal agar medium and black when grown on yeast or malt extract. The spares are borne solitarity and are brownish-olive in colour. In order to get the substance BU4664L, it is said that it can be grown either in an organic or inorganic medium but better results can be achieved if grown in an organic medium with stirring or aeration. It is said to grow in conditions varying from PH 6+09 and a temperature range of 160—450C, but the optimum ranges are given as a PH near 7 (neutral) and the temperature of 240—360C that makes the medium ready to be used to isolate the substance in 15 days. The patent discloses the method of isolating the compound from the medium. Since the patent and the claims seems as if it is intended to cover the compound and its uses, the detailed description of Micromonospora sp. M990-6, does look unnecessery. However, the real reasons for doing so become apparent when the whole patent document is carefully read over.

A patent is issued only for new inventions which could either be a new product or a new process of doing or manufacturing a thing. Some countries even afford patents to animals and plants, but here too they have to be new. The extent of an invention, as covered in a patent, is defined by several statements known as claims, which expresses the invention in a summarized manner. The usual practice in filing patents is to draft the claims to obtain the widest possible cover of protection to the new invention. Generally, each claim summarizes an essential feature of the invention that needs to be protected. Therefore, it is surprising to note that this patent has only two claims. The first claim covers the compound and its pharmaceutically acceptable salt, the second claim covers a product containing the compound or an acceptable salt, together with a pharmaceutically acceptable carrier.

However, a careful reference to the summary of the invention and the detailed description of the invention reveals that the document clearly covers all the following aspects of the invention:

1. The compound BU4664L produced by Micromonospora SP M990-6

2. Pharmaceutically acceptable salts of BU 4664L

3. All derivatives of the compound BU 4664L

4. All compositions containing one of the above compounds, together with pharmaceutically acceptable carriers.

5. A biologically pure culture of Micromonospora SPM990-6

6. All BU4664L producing strains, mutants or variants of the said organisms which can be produced from the known organism by known means such as X-ray irradiation, ultra-violet irradiation, treatment with phage exposure, or through the use of recombinant genetic engineering techniques.

7. Methods of preparing the compounds in the invention by cultivating the Micromanospora SP M990-6 under aerobic conditions

8. A method of treatment for inhibiting memmalian tumor cells

9. A method of treating pulmonary conditions, inflammations, cardiovasculer conditions and skin conditions.

The widely held view is that a claim should clearly define the monopoly claimed in a patent to make it clear the limits within which the monopoly exists. In other words, claims should set out the limits and not expand the monopoly. The approach in this patent is quite different and unfamiliar. The ability to produce the patented compound BU4664L had been used to cover all organisms that can produce this compound. The statement "any varient that can be produced from the described organism through recombinant genetic engineering techniques is wide enough to cover all organisms, however different, which are produced to make the compound BU 4664L by inserting the relevant gene. It becomes clear why they made a detailed description of the microbe. That is because it is the only known producer of the compound which has also get covered through the compound. Since the microbe is not a "new organism", it cannot be patented, but they have circumvented the problem by patenting all aspects relating to it through the discovery of the useful substance produced by it.

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The patent describes the purified compound BU4664L as a pale yellow amorphous powder insoluable in water, but soluble in methane, ethenol, ethyl acetate and dimethyl sulfoxide. It can be administered orally, as injections or through the anus. Since it does not dissolve in water, it is recommended to be made into suspensions, emulsions or to water solutions containing ethanol in which it dissolves. In addition, it states that this compound could be administered as a powder, as pills, tablets and capsules. In giving it through the anus, it is recommended to make suppositories containing the powder, together with a low-melting wax and cocoa butter. It says that the dosage could vary from 5 to 100 mg per kilogramme of body weight at one time with a daily dosage in the range of 15 to 300 milligrammes per kilogramme of body weight.

This compound is said to possess antitumor activity and effective against memmalian tumor cells and in particular against human tumarcells such as leukamia cells, melanoma or skin cancer cells, celeorectal carcinoma cells and colon carcinoma cells. It is found to kill, suppress and destroy tumor cells resulting in the reduction, and elimination of tumors. In addition, it had been found to be effective against a wide variety of ailments. The patent state that it can be used to treat pulmonary conditions, inflammation, cardiovascular conditions and skin conditions in general and specifically for erosive gastritis, erosive esophagitis, inflammatory bowel diseases, haemorragic erosions induced by ethanol, hepatic, schemic damage or necrosis of liver, pancreatic, renal or heart tissues brought about by poisons, schemic renal failure, liver damage brought by illnesses, pancreatic or gastric damage by bile salts and cell damage induced by stress and trauma.

This very wide range of therapeutic uses proves the significant importance of this substance as a drug and the possible huge rewards brought by it once production starts on a commercial basis. It is quite possible that a variety of preparations containing this compound in one or more forms may be brought to the market. *The Bristol-Myers Squibb Company and the so called inventors will derive huge profits from these sales, but Sri Lanka, from where this microbe was discovered would not get any benefit, nor are we able to exploit it to our benefit. The only satisfaction to Sri Lanka would be that it has been acknowledged in the patent as the type locality of this microbe.* The Convention on Biological Diversity (CBD), while stating the principle of "equitable sharing of resources" does not provide any solution for a situation such as this. The Trade-related aspects of Intellectual Property Rights Agreement (TRIPS) is silent on this as well. Ironically, under Article 28 of TRIPS, we are prevented from making, using or selling any preparations containing BU4664L, as it is already covered by the U.S. patent. *It is high time that we look at these conventions from a national perspective and not in haste to fulfil international obligations about which developed countries do not care much.*

In 1998, Mr. R. Saha of TIFAC, India had said that Bristol Myers Company had patented a new antibiotic complex BU2313, useful for treating anearobic becterial diseases, isolated from Actinomycetes Strain no E 864-61, collected from a soil sample in Rajastan and the inventors have been Japanese living in Japan. A search of the USPTO database traced this patent (U.S. 4,169,096 of 25.09.1979). It deals with a complex of compounds produced by strains of Micropolyspora caecia strain no E 864-61 and have several similarities to the patent U.S. 541,181. Both have been assigned to the same company, the inventors are from Japan (though different individuals), there is no mention of any local collaborators and no benefits to the country from where the microbe originated, and the two microbes, by a coincidence, belong to the same group and family. The difference is that in the Indian microbe, the patent covers only the compounds and its uses and not the microbe and any others made by using it, as in the case of our pirated microbe.

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