PR 5418

A prudent counter-move against patent pirates

By Jagath Gunawardena

A consignment containing 1,000 kilos of Kotala-Himbutu parts intended for Japan was recently sized by the Sri Lanka customs and was followed shortly by the confiscation of a stock of more than 35,000 kilos of Kotala Himbutu parts at Polonnaruwa. These two incidents have once again brought the issue of Kotala Himbutu plants (Salacia reticulata) into focus. In June 1998, similar large quantities destined for Japan were seized by the customs and then it was revealed that the Japanese Company Jintang had prepared and is marketing products based on Kotala Himbutu to treat diabetics and as diet pills and that the same company had even obtained a patent covering the use of this plant in the treatment of diabetes. The use of a boiled concoction of Kotala Himbutu is a well-known, easy to prepare effective and therefore a popular remedy for treating high-blood sugar in Sri Lanka and is part of our traditional knowledge. The news of the patent and products was greeted initially with some disbelief, but quickly generated anger, revulsion and disappointment, when it became clear how our rights have been violated. At the same time, there were attempts by vested interests, working under the cloak of anonymity to twist the facts and misinterpret information in order to show that media personnel and eco-activists are dishing out incorrect information and that there were no patents as claimed. The truth was that, at the time there were two patents covering the use of Kotala Himbutu in the treatment of diabetes.

The search for patents based on Kotala Himbutu (Salacia reticulata) revealed four, two in USA and the other two in Japan. A problem in perusing Japanese patent documents is that they are in the Japanese language and only a summery is available in English. Three of these patents directly covers compounds from this plant in the treatment of diabetes. One patent (US 5,650,167) titled "Method and Composition for treating hepatitis B" covers a range of compounds and the way they are used (treatment methods) to cure Hepatitis B in mammals. One compound covered in the patent comes from Kotala Himbutu. Although the title, abstract and the background of the invention mentions only Hepatitis B, the description state that the compounds covered can be used to treat other diseases such as diabetes, nephritis, rheumatoid arthritis, organ and celluar transplant rejection, septic and traumatic shock. This patent really covers the treatment method but has used the claims to extend the coverage to all such compounds that can be used in the method, but not the compounds themselves. It is a process patent covering therapeutic methods and not one that covers a product.

The other three, in contrast, covers products derived from the Kotala Himbutu plant. The most extensive in scope and detailed in the description is the US patent no US 5,691,386 of 25/11/1997, titled 'Triterpenoid compound for the treatment of diabetes'. The inventors named are Wayne D. Inman and Michael John Reed and the patent is assigned to Shaman Pharmaceuticals of San Francisco, USA. It has 13 claims which cover the compound, its purified form that can be used for the reduction of blood glucose levels, all pharmaceutical salts of the compound, a mixture containing this compound with other orally given hypo-glycoemic agents blood-sugar reducing drugs like Metformin,Buformin, Acarbase, Miglatol and Troglitazone. (Claims 3 to 8). All methods of treatments to reduce blood glucose levels using the compound alone or as a mixture are covered by claims 9 to 13.

One of the three basic requirements for a patent is that it should be for a new or novel invention, or for something that had not been previously known. The compounds that is covered by the patent cannot be deemed an invention since it had occurred naturally within the tissues of the plant, although not known to man. What had been done by the scientists is to isolate, identify and then ascribe a use for this particular substance. It is only a discovery of something that had been in existance in native. Discoveries, if they are new, are considered as inventions by the patent laws in some countries, notably in USA where many of these have been patented. The relevant law in Sri Lanka, the Code of Intellectual Property Rights Act No. 52 of 1979, explicitly excludes the patenting of discoveries (Section 59 (3)). This difference was deliberately made use of by the vested interests in the past to misinform the public by citing the Sri Lankan law when the real issue was the patents issued in USA and Japan where discoveries are treated as inventions.

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The requirement of being novel or something that is not known previously differs according to countries. Since it is not possible to define what is new, the laws adopt the position that "what is not previously known" is new. The existing knowledge is often referred to as prior art, or knowledge that is already available to the public. This often makes one to assume that a product based on traditional or existing knowledge is not patentable as it lacks novelty, in addition of it being a discovery and not an invention. An active ingredient found in a plant is the basis for a particular use. Therefore, it can be said, that although the active ingredient had not been isolated, the existence of such had been known by the particular use, or it had been anticipated by prior art. In this perticular case. Since the use of Kotala Himbutu extract had been proven to be effective against high blood sugar, the possible existence of the compound that was subsequently isolated and identified and probably some others showing the same properties had been anticipated by prior art.

This patent is yet another good example of how narrow the definition of prior art is being adopted by countries like USA. The background of the invention says (page 3) that "plants of the genus Salacia have been used in India and South-East Asia, including Sri Lanka to treat a variety of ailments. It adds that "a hot water extract of S. prinoides have been taken orally as an anti-diabetic and an aqueous extract of the roots of S. reticulata have been used to treat diabetics mellitus in Sri Lanka (page 4). This statement is a clear acknowledgement of our knowledge. They have in addition cited two research papers by Sri Lankan scientists on the anti-diabetic properties of S. reticulata. One is from the Journal of Ethnopharmacology Vol. 13 (1985) titled "Mangiferin from the root bark of S. reticulata, by Professor E. H. Karunanayake and others. The other from Phytotherapy Research Vol. 4,No. 5 (1990) titled "Oral-hypoglycaemic effect of S. reticulata in the Streptozotocin induced diabetic rat, by Dr. Palitha Serasinghe and others. Scientific data in published journal articles are in the public domain and for the purposes of patents form a part of prior art. This example proves that not only the traditional knowledge but even recently proven scientific data already available to the public does not necessarily become part of prior art to prevent novelty in a patent if they can make a slight difference (in this case isolation and identification of the compound). This shows that there definition of prior art is quite narrow in scope makes it possible to use traditional and new knowledge in order to discover active ingredients and claim monopolies not only over such substances but to cover the associated knowledge. This answers another misconception that if we can make information on traditional knowledge and practices to be available widely (for instance by putting in the Internet), it would make them prevent others patenting products or processes based on our knowledge. Instead, such moves would greatly facilitate others to use our knowledge base to easily obtain new discoveries and claim monopolies.

This position is made more clear by the justification for the so-called invention in this patent, spelt out under the background of the invention which are as follows:

*** A plant could contain one or more compounds with a 'desired' biological activity.**

*** At the same time there could be one or more compounds that could contradict the desired activity.**

*** Medicinal plants may contain other compounds that can be toxic.**

*** When administered as a plant extract, the dose is difficult ro regulate.**

*** Therefore, there is a need for a purified form of the active compounds useful as a hypoglycaemic agent, a composition containing effective amounts and methods of their use.**

This justification cannot justify the company having a monopoly over the compound and all other aspects, including methods of treatment. A method of treating an illness cannot be claimed in a patent in Sri Lanka as we believe that such things should be widely available for the greater good of the public. However, methods of treatment and diagnostic methods of illnesses can be covered by patents in USA.

The Japanese patent JP 9301882 of 25/11/1997 is titled "Anti-diabetic agent and its production". The inventor named in it Yamahera Joji and is assigned to Morishita Jintan of Japan. The patent states that the invention covers an antidiabetic agent extracted from the dried leaf, bark, root sheath, woody parts and other parts of Salacia reticulata. The extraction can be done either with water or with an organic solvent such as alcohol and then concentrating the extracted liquid. It can then be mixed with a carrier to be made into pills or powders. The concentrated liquid can be added to food stuff. The effective dose is stated to vary from 5 to 200 milligrammes per kilogramme of body weight. The active compound had not been isolated or identified by name. It is identified only by the desired activity which is given as inhibiting the action of a sucrose decomposition enzyme and having high safety for use.

The second Japanese patent JP 11 049692 of 23/02/1999 is titled "Anti-diabetic agent and food product containing the same". The inventor in this is also Yamahera Joji and is again assigned to Morishita Jintan. The purpose of the invention, stated in the patent, is to provide an anti-diabetic agent that can be given by mouth that can inhibit the absorption of glucose to blood. This patent covers a composition where the essential ingredient is an extract of Salacia reticulata. It is mixed with an extract of any of the following which are Marmardica Charantina (Bitter Gourd or Karawila), Gymnema Sylvestre (Mas-bedda) Beta vulgoris (Beet), Achyranthus spp (Karal-Heba) or Anacordium occidentale (Cashew). Of these, Bitter Gourd, Mas-bedda and Karal-Heba are all known in our traditional medicine as having anti-diabetic properties.

These two Japanese patents share the same inventor and assignee. They cover an extract of Salacia reticulata without identifying an active ingredient. The effectiveness of an extract of S. reticulata to treat high blood-sugar is part of the traditional knowledge of Sri Lanka and its effectiveness had been scientifically proven by our Scientists. In addition to the two scientific papers cited as references in the US patent, an earlier paper by Professor E. H. Karunanayake, Drs. J. Welihinda, S. R. Sirimanne and G. Sinnedorai titled "Oral hypoglycaemic activity of some medicinal plants of Sri Lanka in the Journal of Ethnopharmacology vol. 11 (1984) has shown the effectiveness of S. reticulata, Karawila and Beli (Aegle marmelos) in controlling blood sugar. The team of Japanese scientists testing S. reticulata extracts on rats and human beings and showing its effectiveness is nothing new, but only a further elaboration of a fact that had been traditionally known and confirmed subsequently by our scientists. There is nothing novel in it, but accepting it as such is profitable for the company and advantageous for Japan by way of profits.

The assignee of these two patents, Marishita Jintan had prepared an anti-diabetic pill which was in the market in 1998 as a green coloured tablet, to be taken during meals. The same company had introduced another tablet which translates into English as "Salacia diet pill." It is recommended to those who either wants to reduce weight or to stop getting fat without reducing the intake of sugars or starchy foods. Both these preparations inhibit enzymes and reduce the absorption of glucose to the body. Another form of using the extract of S. reticulata had been to add it to sweet foods which are then labelled as diet food because the absorption of sugar is less, helping them to consume more food without putting on weight.

These three patents effectively preclude Sri Lanka from exporting any value-added product with Kotala Himbutu extracts to reduce blood sugar or even as diet preparations. It, however, does not prevent exports of raw material, which will give our country a meagre income, but, would help the assignees of these patents to make products and earn large profits, at our expense. There are three broad options available in the face of such misappropriations of our natural resources and knowledge. One is to challenge the patents in USA and Japan, an exercise that is costly time consuming and difficult and could be unsuccessful at the end. The second option is to export the raw materials and earn a small amount. This had been slyly promoted by vested interests who had been claiming that the continued exports of Kotala Himbutu is profitable to the country and is wrong to stop them.

The third option is to stop all exports of raw materials. The holder of a patent needs to make periodic payments to maintain it and if it does not bring any income, holding on to it will incur loses. In this instance, if they are deprived of raw materials, they would not be able to gather any profits. After several years, companies abandon patents as it drains their finances without any gains. This is a clever war strategy known as "taking firewood from under the cauldron", used to counter an opponent who has the edge by depleting his resources and not confronting directly. Here too the companies have the edge (patents) and have to be defeated by depleting the resources (raw material). The position taken by the Forest Conservation Department in not giving permission to export Kotala Himbutu is farsighted, prudent and praiseworthy.

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