

PR 5407

Patent piracy of Pila: monopolies over traditional knowledge

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A patent is given to an invention that meets the three basic criteria of novelty, non-obviousness and usefulness. Some countries grant patents to certain types of discoveries if they satisfy the three basic criteria. Since it is not possible to define what is new or novel, it is done by stating what is not considered as something new or what is already known, often referred to as prior art. Prior art means any previous disclosure or use of an invention in any part of the world. Disclosure could be by any written communication that is published, including other patents or the making or using of the invention. In some countries, including Sri Lanka, prior art includes oral communication within the country. The distinction between prior art and what is considered as new varies according to countries. In some, any improvement on something that is known already is considered as new. It is this narrow definition of what is new, coupled with giving patent protection for discoveries that had made it possible to obtain a patent for a discovery based on traditional knowledge, often associated with the therapeutic use of plants. In some, the active ingredients that provide a desired effect have been isolated, identified and covered in patents as "new discoveries". Others have not identified an active ingredient, but have got claim to cover any extract or a mixture containing an extract that gives the desired effects. Several patents obtained in other countries, notably in U.S.A. and Japan fell into these categories.

The two patents involving traditional treatments and uses of the Pila plants (*Tephrosia spp*) fall into the second category where the active ingredient is not known but is claimed to be in an extract of plant material that can bring about the desired results. Several species of plants belonging to the genus *Tephrosia* are found in Sri Lanka and are known in Sinhala as 'Pila'. They grow as small shrubs and herbs and some are quite common in the dry zone. All have compound leaves with several pairs of small leaflets and small flowers borne on inflorescences. The flat seed pod (legume) has several small, hard seeds. The different species are

identified by the size and colour of the flowers which varies from white, pink and mauve to orange, the number of leaflets in a compound leaf and the characteristics of the leaves. The most widespread and common is *Tephrosia prepeurea* that has small dark mauve flowers. It is often called "Katuru-Pila" in Sinhala because the closely arranged veins in the leaflets make it break along clearly as if cut by a pair of scissors.

In Sinhala traditional medicine, Pila is mostly used as widely known folk remedies (ath-beheth in Sinhala) than as elaborate preparations. The root is crushed or boiled and used as a mouth wash to keep teeth and gums healthy, to cure bad odour of the mouth, to cure boils and sores in the mouth. Pila roots are washed and dried to be used in brushing teeth or in preparing tooth cleansing powders. Some villagers have the habit of uprooting a Pila plant, wash the root and then chew an end into a crude brush to clean their teeth in the morning. These traditional uses have provided the basis for the Japanese patent JP — 60054312 of 28.03.85, obtained in the name of Nissan Isurui Yakuhin company of Japan titled "Preventive for dental caries". It covers 12 species of medicinal plants found in Sri Lanka including *Tephrosia purpurea*. A patent application in Japan should be in Japanese and the patent is also published in Japanese language. A summary is published in English to help patent examiners in other countries in their search for "prior art". The invention in this particular patent is a water extract or an alcoholic extract of the plant that can be used in preparations like toothpastes, gargles, ointments, chewing gums or any other preparation for the prevention of caries in teeth.

The patent itself states that their invention is based on a herbal preparation used in Sri Lanka for the same purpose, is safe and effective in preventing dental caries it is an admission that the use of the plant for the prevention of dental caries was known previously. Furthermore, no active compound from the plant had been iso-

lated and identified. The effective component is identified only as an "alcohol or water extract". This extract could well contain more than one active ingredient. The only thing that is really new is the claim that the extract effectively destroys bacteria such as streptococcus mutans. Sanguis and *S. Mitis* that are responsible for causing dental caries. This is novel only in a very narrow sense, because the effectiveness had been known for generations, though not

The patent states that this extract is effective for several conditions and can be used to cause slimming of bodies, to reduce signs of aging, to cause pigmentation and to treat inflammation by applying on the skin or taken orally for slimming and reduce aging. The roots of Pila plants (Pila-mul in Sinhala) had been widely used to treat scars left by burns, infections such as chicken pox or by wounds by applying a poultice of crushed roots.

proven by laboratory experiments on bacteria. Therefore, what is considered as new is only a confirmation of an already known effective use.

The other patent covering used of Pila plants is U.S. 5,709,864 of 20.11.1998 titled "Cosmetic or Pharmaceutical and particularly dermatological, composition containing an extract of tephrosia, particularly tephrosia purpurea". Although the patent has been obtained in USA, it is assigned to Parfums Christian Dior of France and the "inventors" are all residents of France. This patent has 35 claims in all. There are five main claims and the rest covers various aspects of these main claims. This patent covers an extract of the plants of the

genus *Tephrosia* that had been obtained by extraction with water, ethylalcohol or methyl alcohol. No active ingredient has been isolated or identified. The first claim covers "an extract of a plant of the genus *Tephrosia*" that can bring about the desired effects. The first example cited in the patent states that a kilogramme of seeds yielded 80 grammes of concentrated extract and the second example shows that 2.365 kilo grammes gave 58 grammes of extract which was like a brownish gum.

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According to the patent, they have unexpectedly discovered that an extract of *Tephrosia* acts as a powerful stimulant in activating the enzyme adenylate cyclase (page 6 of the patent) and thus could be valuable in cosmetics and pharmacology, in particular in dermatology to obtain body slimming, anti aging, anti-inflammatory and pigmentation effects. However, there is no mention about what they were working on when this unexpected discovery was made. It is quite possible that they had

been working on to determine the validity of some traditional practices. It is common to target research on plants, based on traditional uses in the source countries in isolation of active ingredients. The discovery of the way how the plant extracts of Pila work on the body have made it possible to use it in a wider range of applications some of which were previously unknown and therefore could be justifiable to be called as new innovations.

The two patents on Pila (JP 60054312 and U.S. 5,709,864) share several similarities. There is no identification of the active ingredients but made their claims over an extract in which the still unknown active ingredients are found. The presence of this undiscovered active ingredients is determined by the ability of the extract to produce the expected result. They both lay claim over yet unknown compounds which leave room for further claims and effectively block research by others on the same fields. Both have relied on the traditional knowledge and practices in Sri Lanka. The innovation in the first patent and at least part in the second are confirmation of the effectiveness of the traditional practices. The patents have been awarded to firms outside the range of occurrence of the plants.

The important difference is that the first patent covers only the extract made from *T. purpurea* whereas the second covers on extract of any plant species of the genus *Tephrosia*. The second patent is wider in scope and is therefore the monopoly granted are more restrictive. These wide monopolies would effectively prevent the development of any product by Sri Lanka and India where these plant occur naturally. This is because member states of the World Trade Organization (WTO) are bound by the Trade Related-aspects of Intellectual Property Rights (TRIPS) agreement and Article 28 obliges member states to prevent an import of a product made in infringement of a patent obtained in another member state. We are not precluded from using Pila plants for these remedies within the country but would be prevented by using the traditional knowledge and wisdom of the country to our own advantage as it has now become part of the monopoly claims of foreigners.

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