

Bio-piracy and the legal regime in Sri Lanka

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The taking of Intellectual Property Rights (IPR) over the biological material, including genetic material, has been a problem confronting Sri Lanka for the past three decades. It is known as Bio-piracy and is usually, but not always, associated with the export of biological material. What happens in Bio-piracy is the gaining of exclusive monopoly rights over the biological material of one country by individuals, institutions or companies of other countries that leads to the restriction of the obstruction of, or the denial of the rights of the country of origin. This infringement of the rights prevents, restricts or interferes with the use of the material and products. This has nothing to do with the physical loss of the biological material but denotes the loss of rights. The act of bio-piracy involves the use of force as it is in other types of piracy, but the difference is that the force is exerted through the intellectual property laws.

The intellectual property tool widely used to commit bio-piracy is the Patent, while there are a few instances in which it is a Plant Breeders Right, which is known as the Plant Variety Protection Right in some countries such as the U.S.A. It is interesting to note that the incident that led to the coining of the word bio-piracy was committed with the help of the Plant Variety Protection Rights, in which a resident of U.S.A got two Plant Variety Protection Rights certificates for two coloured cotton varieties that are indigenous to Peru. The Canadian public interest body then known as RAFL, which publicized this incident in 1993 coined the term bio-piracy to describe this activity and the term has since become popular and has been used widely.

The law that provides for the granting of IPR in Sri Lanka is the Intellectual Property Act, No.36

of 2003. This, however, does not cover the Plant Breeders' Rights. An Act to grant Plant Breeders Rights in Sri Lanka has not yet been passed and hence the possibility is there only for obtaining patents. According to Section 63 of this Act, an invention is patentable if it is new, involves an inventive step and is industrially applicable. The term invention is defined (in Section 62(1)) to mean an idea of an inventor, which permits in practice the solution to a specific problem in the field of technology. According to Section 62(2), an invention may be, or may relate to a product or process.

An invention has to fulfill the following three criteria for it to be eligible for a patent;

1. It has to be new – Novelty

Since there is no way to define what is new, the Act defines what is new by defining what is not new. Accordingly, Section 64(1) states that an invention is new if it is not anticipated by prior art. The term "prior art" is in turn defined in Section 64(2) and shall consist of;

- (a) Everything disclosed to the public, anywhere in the world, by written publication, oral disclosure or the use in any other way, prior to the filing or, where appropriate to the priority date of the patent application claiming the invention.

However, there are two exceptions to this, which are,

- i. If the disclosure has happened within one year preceding the date of application and is the results of activities by the applicant or predecessor in title,
- ii. If the disclosure happened within six months preceding the date of application and is the

consequence of an abuse of the rights of the applicant or the predecessor in title.

- (b) The content of a patent application made in Sri Lanka having an earlier filing date, or where appropriate, a previous priority date.

2. Inventive Step/Non-Obviousness

This is defined in Section 65, which says that an invention shall be considered to involve an inventive step if having regard to the prior art relevant to the patent application, the step should not have been obvious to a person having ordinary skill in the act.

3. Industrial Application/Usefulness

This is defined in Section 66 which says that an invention shall be considered industrially applicable if it can be made or used in any kind of industry

However, any invention that meets these three criteria are not awarded a patent if it falls within one of those that are stated explicitly under the exclusions as set out in Section 62(3).

Among these are;

- i. Plants
- ii. Animals
- iii. Micro-organisms except transgenic micro-organisms
- iv. Essentially biological processes for the production of plants and animals
- v. Methods for the treatment of the human or animal body by surgery or therapy
- vi. Diagnostic methods practiced on the human or animal body.

In addition to these restrictions, according to section 62(3)(f), a patent can be denied to any invention if there is a need to prevent it being commercially exploited within Sri Lanka in order to protect the public order or morality, including the protection of human, animal or plant life or health or the avoidance

of serious prejudice to the environment. The word public order is derived from the French term “*Ordre Public*” which means “the well-being of the society”. In using the provisions of Section 62(3)(f), the merits and demerits of the invention has to be studied.



The exclusions listed in the Act show that the only living beings that could be patented are



transgenic micro-organisms. The term “transgenic micro-organism” is to be interpreted according to the interpretation of the word “transgenic” in

Section 212 of this Act which is “an organism that expresses a characteristic not attainable normally by the species under natural circumstances, but which has been added by means of direct human intervention in its genetic composition.” Biological material, including bio-chemical compounds and genetic material cannot be patented as they are discoveries, but not inventions. However, it is possible to get a patent on a novel gene construct if it satisfies the three criteria. The IPR system in Sri Lanka has effectively prevented any abuse of biological material by getting patents.

However, it is seen that in some countries such as U.S.A., a discovery can qualify as an invention and thus become patentable. Hence, it is important to prevent any unauthorized export of biological material and to subject all legal exports to a Material Transfer Agreement (MTA) that lays down all relevant aspects



such as the granting of IPR to processes and products and the sharing of profits. Therefore, the laws that regulate the export of animals and plants also play a crucial role in preventing bio-piracy by regulating and controlling all exports.

The export of any wild animal or their parts, and plants are regulated under the Fauna and Flora Protection Ordinance. According to Section 40, no person can export any animal (living or dead) or any part of an animal except under a permit issued by the Department of Wildlife Conservation. Such permits can, according to Section 40(2), be issued only for the promotion of scientific knowledge including supplies to museums and zoological gardens as supplies and in exchange for others.

It is stated in Section 40(3), that the provisions of Section 40 shall have the effect as if it formed part of the Customs Ordinance and therefore the provisions of the Customs Ordinance will apply accordingly.

The protection of plants is dealt with mainly under the provisions of Section 42 which makes it an offence to remove, uproot, destroy, or cause any damage to or injury to any plant that is deemed to be a protected species (those that are included in Schedule VIII under this section) or sell or expose to sell any plant or part thereof. Hence it is not possible



to export any plant or part, including extracts, of any plant that is protected as it involves the damage, injury or destruction of a plant.

Section 45 provides for the minister to issue orders by way of regulations to prohibit or regulate the exportation of any plant. This applies to those species that have not been protected. There are two sets of regulations made under this section that have regulated the export of plants belonging to the genera of *Cinnamomum* and *Salacia*. The amendment No.22 of 2009 has provided protection to all species of plants belonging to the genus *Salacia* and therefore the regulations apply only in the exportation of plants or material of plants belonging to the genus *Cinnamomum*.

The Forest Ordinance has regulations that deal with the export of forest produce. The definition of “forest produce” include not only the plants and their parts, but an extract of a plant as well. The regulations published in Gazette Extraordinary No.1161/1 of 05.12.2000 has made it mandatory to get a permit from the Forest Conservation Department for the export of any forest produce. These regulations also cover the export of leaf litter and topsoil that is exported to isolate useful micro-organisms.

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