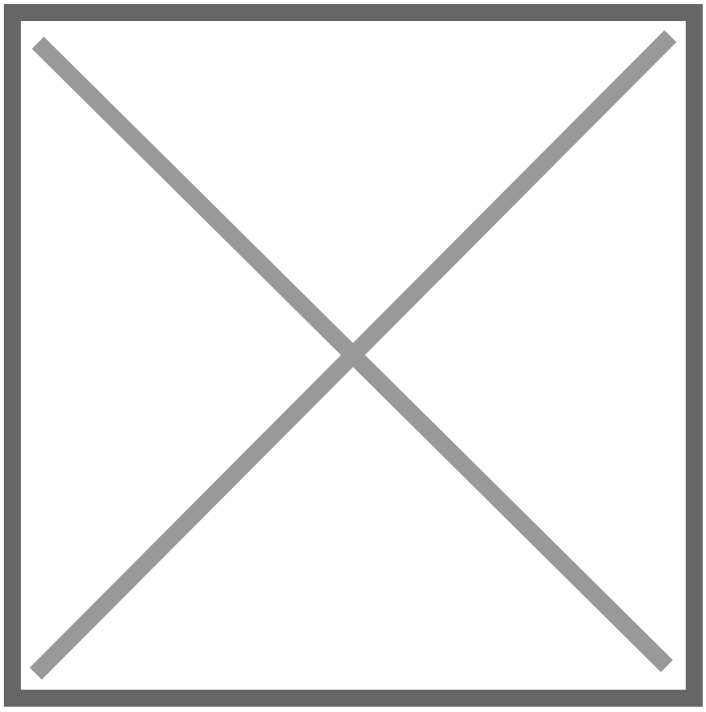
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Green Gold

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LEGAL VIEW

Green Gold

A method of treating a surgically inflicted wound by applying turmeric powderÃ¢â?¬Â¦ Doesn't it sound like what your grandmother taught you years ago? This was the turmeric patent that eventually got knocked off. Are we the only sitting targets?

Salagen is the new pill for xerostoma, the dry mouth syndrome, a pill with pilocarpine as its active ingredient, derived from a shrub that was once used by the Tupi-Guarinis tribe of Brazil to induce salivation. The Tupis continue to chew the leaves of the shrub while an American corporation is reaping huge benefits.

Salagen, in fact, is not an isolated instance. Who has not heard or lamented about Neem, Basmati, Haldi or Jamun piracy? Or the Enola bean story? It is estimated that more than 3,000 patents today are plant based and more than 50 percent of the top 150 prescribed drugs in the US are said to be based on traditional knowledge.

Welcome to the valley of green gold, where biopirates are uncrowned kings and nature is the pasture for a quick buck. The new gold rush is not limited to exotic vegetation or soil, but includes isolated molecules, bioactive fractions, gene sequences, plants and herbal formulations.

Biopirates counter that whilst a natural material may have been known to a tribe, refining and isolation of the actual molecule imparting that property from the plant requires effort, skill, systematic study and trials which calls for substantial investments. Hence, intellectual property rights protection is well deserved. But what about erosion of the green cover and recompense to stakeholders/source?

What about the effort of local communities in conserving valuable species, plants and animals and on which they depend for their food and livelihood?

Biopiracy undoubtedly is a serious threat to biodiversity and the environment. It threatens the right of local communities to biodiversity, weakening their ability to conserve natural resources. Its here to stay. Can we control it? The solution may be multi-facetedÃ¢â?¬â?•legal and through government initiatives.

One possible way forward is the defensive method of preparing databases of plants, extracts and their uses, in several languages and make it accessible to patent examiners in various countries. Such databases being foreign "publications" would force the USPTO and EPO to think twice before issuing neem-like patents. India and China have adopted this approach

and it is reported that the database has more than 4500 entries. Such initiatives, if started on a local scale by native Americans and Aborigines of Australia, may be more successful and provide opportunities for conservation of resources as well as possible industrial use.

Hoping that a legal provision mandating conservation of natural resources, equitable sharing and sustainable use of natural resources may make a difference, an International treaty, the Convention on Biological Diversity (CBD), took effect. Nearly 150 countries are members, including India. The CBD legitimizes a market for bio-resources and tries to strike a golden mean between undue exploitation and conservation.

To comply with obligations under CBD, countries such as Philippines have enacted legislations wherein access to biological resources is exclusively on "no permit, no collection" basis and heavy fines are imposed on those in breach. Benefits arising out of utilization of biological resources are to be shared with local communities and such communities are entitled to participate in all levels of decision-making.

Similarly, India has passed the Biological Diversity Act, 2002; the law though is not in force as yet. As per the scheme of the Act, Biological Diversity Boards at the central and state level are to be set up and compensation for use of biological resources is to be paid to the local communities/government.

Other salient features:

- Any person desirous of using biological resources occurring in India for research or other purposes will have to seek permission from the Biological Diversity Board.
- Transfer of resources as well as acquisition of IP rights is subject to permission from the Authority.
- Local communities inhabiting forests are entitled to receive compensation from parties using their biological resources or knowledge
- Non-Indian bodies required to obtain prior approval of National Biodiversity Authority for purposes of research, commercial utilization, biosurvey or bioutilization of biological resources occurring in India or knowledge associated therewith
- Transfer of the results of any research to a non-Indian or a body with foreign equity entails prior approval of the Authority
- The Authority while granting approval may impose benefit-sharing fees or royalties or both. Any contravention of this provision is an offence, punishable with a fine or imprisonment or both.
- Collaborative research projects between an Indian and a non-Indian, including between institutions are to conform to the policy guidelines of the central government and are to be approved by the central government
- Any person, whether Indian or non-Indian, or bodies with foreign equity, shall apply for any IP rights in or outside India for any invention based on research or information on a biological resource obtained in India without the prior approval of the National Biodiversity Authority
- In cases of patents, the permission may be obtained after acceptance but before sealing (grant) of the patent. The Authority may impose benefit-sharing fees or royalties or both for sharing of financial benefits arising out of such research
- Local community is entitled to receive rewards for use of resources and knowledge within their jurisdiction and negotiate with authorities.

The success of this law depends on its implementation. For now, it is the Patents Act, 1970 that makes it mandatory for a patent filer to mention the geographical source and origin of a biological material used in an invention. Absence of such a disclosure or failure to disclose could potentially lead to revocation of patent. Costa Rica is reported to have a similar law. Although it may be quite difficult for one to track patents granted and whether they have indeed used any biological material owned by a local community, it is a step towards conservation of biological resources.

The Patent Bill 2003 mandates obtaining of "prior informed consent" of the right holder even prior to filing of a patent application. While obtaining "prior informed consent" may pose significant hurdles in obtaining patent rights, it is yet another step that will have to be tested on the touchstone of implementation.

Government initiatives by way of policies may also go a long way in promoting conservation of natural resources and improving livelihoods of indigenous communities. Such as contracts between a company and the local communityÃ¢â?¬â? the Merck model wherein Merck, in 1991, in exchange for rights to screen, develop and patent new products from plants, microorganisms and animals, paid about $1.1 million to local bio-diversity program and the national environment ministry of Costa Rica. The contract also had a clause for return of unspecified percentage of royalties earned from resulting products.

Back home, an Indian tribe has shown by example what "equitable benefit sharing" means. A group of scientists from the Tropical Botanical Garden Research Institute (TBGRI) while conducting a survey in the forests in the Agasthya Hills, Kerala, found that the secret of energy of the local Kanis lay in a berry that they ate. The plant producing the magical berries is locally called Arogyappacha and has been grown and used for generations by the members of Kani tribe. This plant was later identified as Trichopus zeylanicus ssp. travancoricus. Detailed chemical and other investigations led to the identification of glycolipids and other compounds with immuno-enhancing properties. The fruits had anti-fatigue properties. TBGRI developed a herbal formulation Jeevani containing Trichopus, which adorned the shelves of every pharmacy in 1995. Half teaspoon of this herbal formulation in warm water with sugar (if needed) is a powerful energy booster and mind relaxing nutritional supplement.

The TBGRI shared royalties earned out of this product with the Kani tribal community and it is reported that a trust has been formed of which 60 percent are members of the Kani tribe. An important aspect of the Kani story is that they had implemented "benefit sharing" even while the concept is to take root in many parts of the world.

Another method may be the use of confidentiality agreements or trade secrets whereby developing countries may license their knowledge to the highest bidder.

Given the insatiable desire of pharma companies to explore and develop new medicines, the need to improve livelihood of indigenous communities and the need to conserve biological resources, denial of access or exploitation is not the answer since it may only encourage underhand means. An equitable solution that brings financial rewards and conserves biological resources, technology transfer, employment and eventually leading to national prosperity is the future picture and all initiatives must be headed in that direction. Is anyone listening?

Rajeshwari, K& S Partners: rajeshwari@knspartners.com

J Sagar Associates is a leading national full service law firm and K& S Partners is an IP focused law firm. Both the firms provide legal services to several domestic and international biotech clients. Henceforth senior people from these companies will write on the patent issue.

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