

Building the Golden Triangle

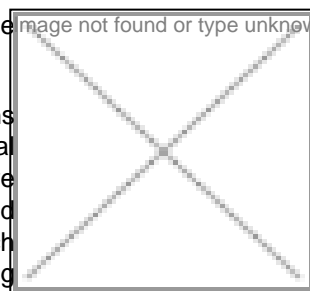
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There is an urgent need to build a strong bond between the traditional medicine, modern medicine and modern science.

This realization seems to be dawning on our institutions now. I will begin at home. CSIR happens to be the largest chain of publicly funded industrial R&D institutions in the world. We are a formal system of innovation and we had closed our mind to informal systems of innovation. But we are changing now. I will cite an example to illustrate the point. It concerns our 20-laboratory networked program on discovery of bioactive molecules for their use as drugs and therapeutics. Our research is based on the clues that we get from our vast plant based traditional medicine systems including Ayurveda. For the first time, CSIR forged relationships with Indian traditional systems of medicine, namely Ayurvedic and Siddha systems. I still remember that when CSIR signed the MOU with Arya Vaidyasala in Kottakkal, Professor MS Valiathan, who brought both the partners together, said, "This is a holy place where two rivers are meeting; the river of traditional knowledge and ancient wisdom represented by Arya Vaidyasala and the river of modern knowledge represented by CSIR". The only question I asked myself was that why did it take almost 50 years after the prophetic words by Nehru for these two rivers to merge? I believe this was because we did not heed the advice of Gandhiji and we "walled our houses on all sides and stuffed our windows". These windows are now opening up.

CSIR's program includes the identification of target therapeutic areas, selection of extracts, discovering of active fractions, molecular description of active fractions, optimization through mixing of fractions from various extracts, understanding the mechanism of action, toxicology studies, clinical trials and discovery of entirely new herbal products which are efficacious,



safe and are reasonably consistent in molecular concentrations.

Currently, under CSIR's New Millennium Indian Technology Leadership Initiative (NMITLI) program, several scientists have been working on establishing pharmacoepidemiological evidence-base to Ayurvedic medicines, practice and development of standardized herbal formulations. Randomized controlled clinical trials for rheumatoid and osteoarthritis, hepatoprotectives, diabetes, hypolipemic agents, asthma, Parkinson's disease and many other disorders have reasonably established clinical efficacy. A review of some of the exemplary evidence-based researches and approaches has also been made. It is clear that we must increase our presence internationally through well-researched publications related to quality, safety and efficacy of Ayurvedic medicines in international peer-reviewed journals. The Ayurvedic, pharmaceutical and medical scientists must come together to make this possible.

Ayurveda and Intellectual Property Rights

There are ways by which modern scientific discoveries are protected through the system of patents. But how do we protect traditional knowledge and products based on it. In particular, the protection of Traditional Medicine (TM) under intellectual property rights (IPRs) raises two types of issues. First, to what extent it is feasible to protect it by using the existing IPR system? Certain aspects of TM may be covered by patents or other IPRs. There have also been many proposals to develop sui generis systems of protection. Such proposals are based on the logic that if innovators in the "formal" system of innovation receive compensation through IPRs, holders of traditional knowledge should be similarly treated.

The grant of patents on non-original innovations (particularly those linked to traditional medicines), which are based on what is already a part of the traditional knowledge of the developing world have been causing a great concern to the developing world. It was CSIR that challenged the US patent No. 5,401,5041, which was granted for the wound healing properties of turmeric. This second Hagi Ghai Ladai, as it has been referred to, has been a path breaking fight for the first time, it asserted the rights of the holders of traditional knowledge from India in international fora. In a landmark judgment, the US Patent Office revoked this patent in 1997, after ascertaining that there was no novelty; the findings by innovators having been known in India for centuries.

Leads on 20 diseases have been obtained. A product called ASMONAe herbal formulation which acts on Asthma is replacing synthetic drugs today. An anti-ulcer herbal formulation which is showing superior even to the best setting synthetic drugs, is going into clinical trials now. There are many leads that a team of around 500 scientists working in an India Team fashion is exploring. I wish such a program had started 50 years ago!

This case was followed by yet another case of revocation in May 2000. The patent granted to WR Grace Company and the US Department of Agriculture on Neem (EPO patent No. 436257) by European Patent Office was squashed again on the same grounds that its use was known in India. India filed a re-examination request for the patent on Basmati rice lines and grains (US Patent No. 5,663,484) granted by the USPTO and Ricetec Company from Texas has decided to withdraw the specific claims challenged by India and also some additional claims.

There is a problem on the grant of such patents linked to the indigenous knowledge of the developing world that needs to be addressed jointly by the developing and the developed world. We need to understand that there is a distinction between the patents that are granted based on modern research and patents which can be categorized as traditional knowledge based patents.

A recent study by an Indian expert group examined randomly selected 762 US patents which were granted under A61K35/78 and other IPC classes, having a direct relationship with medicinal plants in terms of their full text. Out of these patents, 374 patents were found to be based on traditional knowledge not that all of them were wrong.

The governments in the third world as well as members of public are rightly concerned about the grant of patents for non-original inventions in the traditional knowledge systems of the developing world. At international level there is significant level of support for opposing the grant of patents on non-original inventions. For example, more than a dozen organizations from around the world got together to oppose the EPO Neem patent and the entire process took five years. Such a process of opposition is understandably expensive and time consuming.

It is through an Indian initiative that a solution has been found to this problem which has reached an international acceptability now. The Indian government has taken steps to create a Traditional Knowledge Digital Library (TKDL) on traditional medicinal plants and systems which will also lead to a Traditional Knowledge Resource Classification (TKRC). Linking this to internationally accepted International Patent Classification (IPC) System will mean building the bridge between the knowledge contained in an old Sanskrit Shloka and the computer screen of a patent examiner in Washington! This will eliminate the problem of the grant of wrong patents since the Indian rights to that knowledge will be known to the examiner. Hopefully, wrong patents on turmeric, neem, etc., will be the things of the past!

Eventually the creation of TKDL could serve a bigger purpose in providing and enhancing its innovation capacity. It could integrate widely scattered and distributed references on the traditional knowledge systems in a retrievable form. It could act as a bridge between the traditional and modern knowledge systems. Availability of this knowledge in a retrievable form from

many languages will give a major impetus to modern research in the developing world, as this itself can then get involved in innovative research on adding further value to this traditional knowledge; an example being the development of an allopathic medicine based on a traditional plant based therapeutic. Sustained efforts on the modernization of the traditional knowledge systems of the developing world will create higher awareness at national and international level and will establish a scientific approach that will ensure higher acceptability of these systems by practitioners of modern systems and public at large.

The community of Indian research workers contributing to this important task of integrating the ancient with the modern need to always to look for protection of any intellectual property which meets the basis requirements of novelty, usefulness and non obviousness. Can the existing knowledge and products based on them be protected? The answer is 'No'. What preexists, what is in the public domain cannot be protected. Natural products cannot be protected. Further, the preparations that have been used for many years constitute knowledge in the public domain. Therefore, they cannot be patented. However, if new uses are found, a "use" patent can be obtained.

(To be continued)

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