IP Rights and Traditional Medicine: A Procrustes's Bed?

by Philippa Griffin, an Associate at the Patent and Trademark firm Mathys & Squire, specialising in molecular cell biology, biochemistry and biotechnology.

TCM finds a home at Babraham Research Campus near Cambridge

IN ASSOCIATION WITH

As reported previously in Business Weekly, Guangzhou Xiangxue Pharmaceuticals (Xiangxue) recently became the first Traditional Chinese Medicine (TCM) company to establish a base in the UK, at the Babraham Research Campus near Cambridge.

Whereas Western science has tended to be wary of traditional medicine, TCM preparations are 'mainstream' in China – accounting for 30 per cent-50 per cent of the total Chinese medicinal consumption.

Moreover, many important medical advances are based on traditional knowledge: Consider aspirin (originally derived from the willow tree which itself was used for pain relief), and the anti-malarial artemisinin (based on a traditional Chinese medicinal herb).

With the growing awareness of TCM in the West, and global sales of herbal medicines in 2000 alone reaching $30 billion, it is easy to see why corporations want to patent traditional medicines. Accordingly, companies such as Xiangxue are investing in the science underpinning TCM, with a view to identifying new patentable pharmaceutical leads based on compounds discovered in the natural world and used in traditional/ folk medicine.

Against this background, a major concern of NGOs and governments in recent years is protection of traditional inventive and creative activity against misappropriation by third party patenting.

There is a widespread feeling that Western corporations should not profit from traditional knowledge at the expense of the indigenous communities from which it originates. However, at present, there is no legal system in place for rewarding or even acknowledging the contribution of traditional knowledge to modern science.

Recently, the World Intellectual Property Organisation (WIPO) updated its patent classification system to better account for patents relating to traditional medicine based on natural products.

However, as existing patent laws are designed to protect "new innovations", traditional medicine does not fit comfortably into most existing systems.

For example, most TCM products are difficult to define and thus cannot be described with sufficient precision to satisfy the strict requirements of international patent law.

Moreover, as traditional practices are rarely written down, it can be difficult to determine whether they are "publicly known", especially as individual national laws differ in their definition of "the public domain."

The perceived difficulties with the known legal system can lead to what is often termed "biopiracy", and is illustrated by the high-profile example of the "Neem" (Azadirachta indica) Patent cases.

Indigenous communities in India have used the seeds of the Neem tree for medicinal purposes since 5000 B.C, as evidenced by ancient Sanskrit texts. A European Patent was granted to a US company for the anti-fungal use of a product extracted from Neem seeds.

The Indian authorities fought (and eventually won) a 10-year legal battle to have the patent revoked, on the ground that the medicinal properties claimed were known in the "prior art" for thousands of years before the patent application.

As one would expect, publicly available knowledge and practices cannot be patented. However, inventive improvements to traditional medicine may be patentable: For example, other "Neem" Patents were directed to previously unheard of uses, such as the treatment of cancer.

The Neem case highlights a deficiency of patent systems: Searches for "prior art" – i.e. assessment of what is already known – are inherently fallible, particularly because they rely on printed material. To address this issue, WIPO is considering how to improve access by National Patent Offices to traditional knowledge resources.

In parallel, learning from the Neem tree case, the Indian Government is overseeing an ambitious project to collate an encyclopedia of the country's traditional medicine, known as the Traditional Knowledge Digital Library (TKDL).

The aim of the TKDL is to put Indian traditional medicine into the public domain – in particular, to bring traditional remedies to the attention of Patent Office Examiners around the world.

In addition to such "preventative" measures, some argue that "affirmative" mechanisms are essential for regulating the use of traditional knowledge by third parties and providing rewards to communities that have developed this knowledge over many years.

To this end, a number of countries have called for two additional requirements for obtaining patent protection – an indication of biological source when the invention is based on indigenous genetic material, and a demonstration of prior informed consent (PIC) – i.e. confirmation that the community consents to the third party use of their knowledge.

These requirements have already been incorporated into the patent laws of India, The Philippines and the Andean nations.

A further option might be for indigenous peoples themselves to seek protection for new uses of their traditional medicines.

Whilst the expense of patent protection is a major constraint for traditional healers, alternative forms of protection are being considered. For example, trade marks or geographical indications could be used to identify traditional medicines from particular regions or communities.

Some argue, however, that 'Western' forms of protection may be inherently incompatible with the philosophy of traditional communities.

What is evident is that no straightforward, 'one size fits all' answer exists to the question of how best to protect traditional medicine. Further research and debate will no doubt ensue to try to find a solution that accommodates the conflicting needs of traditional communities and modern science.

• For further information, you can either telephone Philippa on +44 (0)20 7830 0000 or email her at: pjgriffin@mathys-squire.com

MATHYS&SQUIRE is not just a firm of patent & trademark attorneys, but a firm of intellectual property experts.

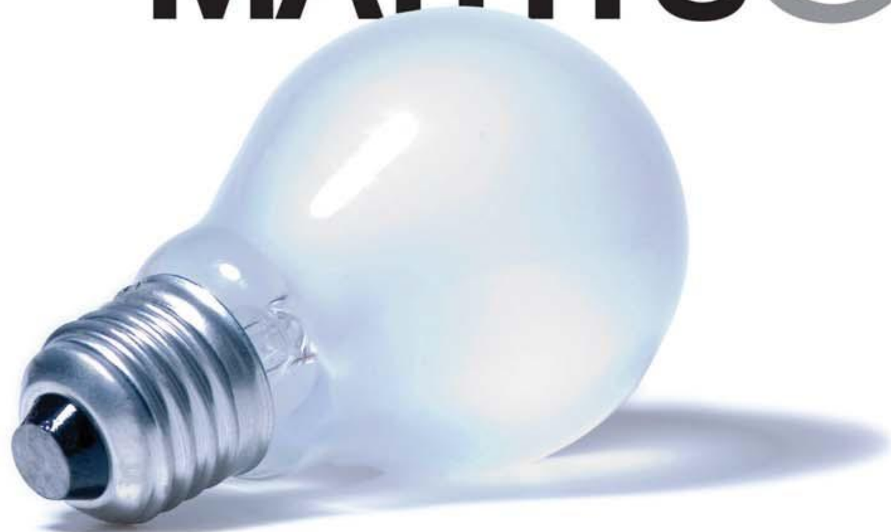
We work by understanding not only your technology, but also your commercial objectives.

We use our experience to develop an IP strategy tailored to *your* business, using patents and other tools, to:

- Protect profit margins
- Create valuable assets
- Support revenue streams
- Manage IP risks

Where IP agreements are required, we can advise you on structures and royalty schemes. We are skilled in the drafting of IP agreements and in the analysis of drafts prepared by others. We have the expertise and experience to negotiate on your behalf.

Innovation & Profit
MATHYS & SQUIRE



Mathys & Squire Trinity House, Cambridge Business Park, Cambridge CB4 0WZ, UK, T + 44 (0) 1223 393739, F + 44 (0) 1223 393738
also at: 120 Holborn, London EC1N 2SQ, UK, T + 44 (0)20 7830 0000, F +44 (0)20 7830 0001
mail@mathys-squire.com www.mathys-squire.com

MATHYS & SQUIRE
INTELLECTUAL PROPERTY