Experiences with the Patent System – A collaborative approach

Mr David Claudie, Kuuku I'yu Northern Kaanju Traditional Owner Custodian, CEO/Chair, Chuulangun Aboriginal Corporation

Dr Susan Semple, Senior Research Fellow, Quality Use of Medicines and Pharmacy Research Centre, University of South Australia



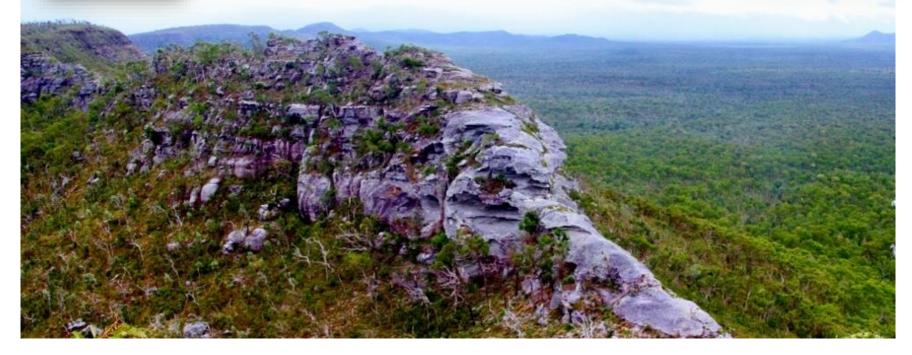


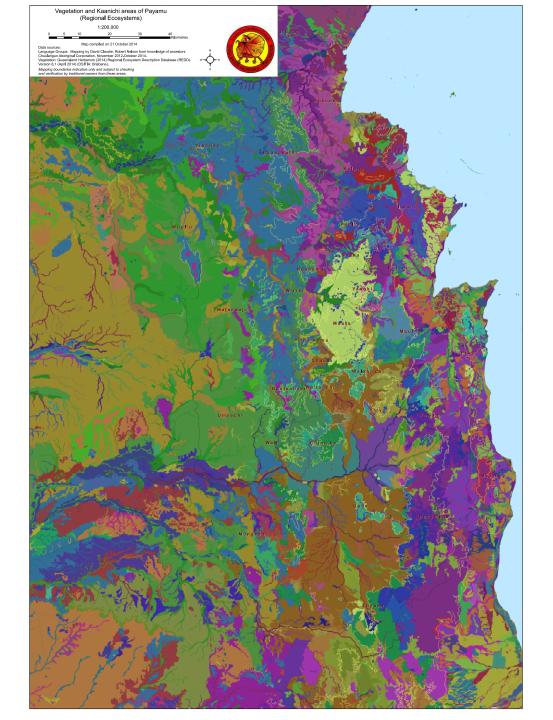


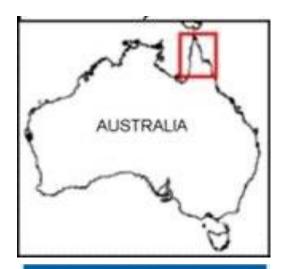
Kuuku I'yu (Northern Kaanju) Homelands or Ngaachi













Chuulangun Aboriginal Corporation

- In 2002, the descendants of a key Kuuku I'yu ancestor who were living on homelands at Chuulangun formed the Corporation
- It is a contemporary extension of traditional governance structures. The 'bloodlines' that tie people to different tracts of land are the foundation of Aboriginal governance, knowledge, land tenure and land management





Kuuku I'yu (Northern Kaanju) Medicinal Plants Project

- Chuulangun Aboriginal Corporation initiated this project in 2003 based on our traditional knowledge and living on homelands.
- This project serves as a model for equitable partnerships and benefit sharing between Indigenous and Western scientific researchers in the investigation of traditional medicinal plant knowledge.
- Collaboration between Chuulangun Aboriginal Corporation and scientists at the University of South Australia.
- Ethical guidelines are a key factor in conducting the collaboration for all parties.







Photos: Dr Nick Smith

Establishing the project

- The collaboration used a participatory action research approach.
- Discussions between Kuuku I'yu and university-based researchers before starting the project examined the aspirations of Kuuku I'yu people in respect of the study and development of their traditional medicinal plants.
- University-based researchers provided advice on the types of laboratory investigations that would be feasible and the legislative requirements for plant-based medicines to be sold as medicinal plant products.
- Key objectives for the research were formulated

Medicinal plants project - objectives

- Investigate extracts from medicinal plants in order to share Western scientific and traditional perspectives for "old and new diseases".
- Allow community members to determine opportunities available for development of plant-products or plant compounds.
- Support the knowledge of Aboriginal Elders by engaging with younger generations, Aboriginal and non-Aboriginal people, on homelands.
- Disseminate information about research processes and findings through collaborative publications.



Collaborative agreement – Jointly developed by Chuulangun Aboriginal Corporation and UniSA

Background IP (traditional knowledge) remains in the ownership of Traditional Custodians and is fully acknowledged in the allocation of any new Intellectual Property (IP) generated

Indigenous
Law and
Custom
govern how
background
IP is used in
the course of
the project

Project
Intellectual
Property is
jointly and
equally
owned by
collaborating
organisations
(Chuulangun
Aboriginal
Corporation
and UniSA)

Decisions to develop Project IP require consent from both parties and partnerships for any development extended beyond the life of the initial funding

Research on homelands

- Plant collection has been undertaken on homelands by Traditional Knowledge holders with expertise in plants and their uses including harvesting techniques, locations and seasons.
- University researchers visit and work on homelands and are led by relevant Traditional Custodians.
- Permit obtained from Biosecurity Queensland for removal and transport of plants and plant specimens.





Plant extraction

- Preparation of extracts for pharmacological testing use traditional methods of extraction where appropriate.
- This has been conducted on homelands by Traditional Custodians who have that knowledge or have permission from the correct Custodians of that knowledge and country.
- Also use laboratory extraction methods (solvents)







Uncha (*Dodonaea polyandra*, Family: Sapindaceae)

- Uncha is a plant used by particular Kuuku l'yu Northern Kaanju Traditional Custodians.
- Decreases pain and discomfort in the mouth from tooth pain, inflammation and infection.
- Plant material (join of leaf and stem) is applied directly to the mouth.
- Based on the traditional uses the team decided to test in the laboratory for anti-inflammatory, antibacterial and cell toxicity effects. Tested ethanol (alcohol) extracts of leaf and stem.
- Both leaf and stem extracts showed significant antiinflammatory activity in a mouse model of skin inflammation, similar to hydrocortisone.





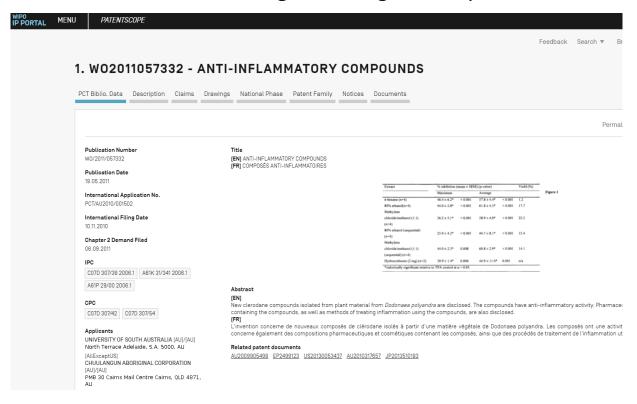
Uncha - Chemistry

- In the laboratory, isolation and identification of components (compounds) from Uncha extracts were undertaken
- A number of compounds isolated from the species were "new" to western science but related to other compounds from the genus Dodonaea – including diterpenoids & flavonoids
- The most active anti-inflammatory compounds are clerodane diterpenoids. They reduced inflammation in a skin model to a similar extent as some of the steroids used in creams for skin inflammation



Uncha: The patent

• WO2011057332 titled, "Anti-inflammatory Compounds" – joint patent application UniSA and Chuulangun Aboriginal Corporation.



Wanted protection and recognition for traditional knowledge – but the mechanisms to do this were limited

Why did we choose to patent?

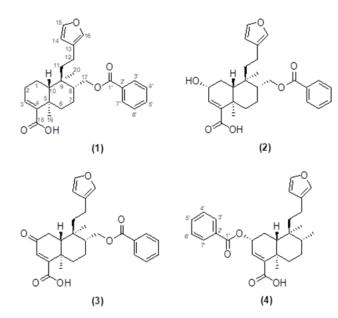
Wanted to be able to publish findings of the research but protect against unauthorized use of the knowledge by third parties.

The anti-inflammatory activity of the extracts and chemical components was significant and had not been shown previously from a western science perspective

Potential commercial development and opportunities for homelands-based enterprises

Uncha: The patent

- Traditional Custodians David Claudie, George Moreton Senior (key Kuuku I'yu ancestor) and university-based researchers named as inventors on the patent.
- Patent now granted in US, Australia and Europe.
- As an example, the US patent covers the compounds, Dodonaea polyandra (Uncha) extracts with compound/s, treatment of inflammation with the compounds or extracts*
- A commercialisation agreement (with equal partners Chuulangun, UniSA and UniSA Ventures), underpins this and determines how we work together and how the patent and the knowledge in it can be used





*There have been some changes to US patenting for natural products in recent years

Uncha: Perspectives on patenting

Positives

- Provides opportunity to exclusively commercially develop the Project Intellectual Property with a 50% share equally to both partner organisations.
- This exclusivity has attracted interest from some potential commercial partners (companies).
- Has given recognition to Traditional Knowledge Holders/Custodians as inventors of the project intellectual property. This recognition has also been reflected in informing government policy in Australia through use as a case study for partnerships in this type of research.
- Once the patent application was lodged, the IP protection allowed the team to publish the research findings about the plant in scientific journals/conference presentations. This was important for other outcomes for the research e.g. scientific recognition of the research, seeking further funding, recognition for research students working on the project.

Uncha: Perspectives on patenting

Negatives or limitations

- Patenting system does not allow for whole clan groups to be named only "inventors" according to narrow definition. However our patent has allowed a key Ancestor to be recognised as an inventor
- Patenting allows only a limited time frame for IP protection, while traditional knowledge has been accumulated over millennia. Once the patent expires the traditional knowledge is in the public domain and no longer protected by the patent. However, in Australia there is a new "Traditional Knowledge Code and Guidelines" in Queensland in line with the Nagoya Protocol.
- The patenting system gives emphasis to the value of the novel and inventive steps from a western scientific perspective, rather than traditional knowledge
- The patent is **narrow** the particular compounds are patented and the particular use (inflammation) but does not cover all potential uses.

Uncha: Perspectives on patenting

Negatives or limitations (cont.)

- Traditional custodians' preference would also be to link IP protection to the particular area of Country. Linking to the clan estates and genetics of plants from that Country. The patent does not prevent others using the genetic material of the plants from the homelands.
- Traditional custodians do not wish to prevent other Aboriginal groups from other Country from developing their own medicines or commercial partnerships based on the same "plant species" (in the Western sense) growing on different Country or the same chemical components in other related plant species.
- Ongoing costs to maintain patents in different countries. Our patent has been a partnership, but patent costs maybe difficult for some community-based Aboriginal or First Nations peoples organisations to afford.

Moving towards commercial development

- First line of any product development for Uncha likely to be whole plant (herbal) product – cosmetic/skin care product for inflammation
- Also fits with Traditional custodians' desire to wild harvest plant material and produce "whole extracts"
- Supply issues are important for commercial partners



Sustainability

- Development of "farms" of plant species off-site would not be congruent with Traditional Custodian beliefs – the plant "needs to pass through our hands" to work properly.
- Obligations under Kuuku I'yu law and custom to 'look after' our Ngaachi in a sustainable manner – in return our Stories, which are the land, will look after us physically, culturally and spiritually
- Sustainable wild-harvest and possibly cultivation businesses on Kuuku I'yu homelands need to be developed
- Mapping of distribution and numbers of Uncha plants on the homelands and effects of harvest and regrowth need to be assessed



Conclusion and practical recommendations

- Develop strong collaborative agreements from the beginning
- Seek legal and commercialisation advice
- Patent system requires 'novelty' e.g. a newly described useful effect such as anti-inflammatory or antibacterial effect which needs supporting data
- Be clear who will bear the patent costs (application process and ongoing maintenance)
- Be aware of the limited time frame for IP protection (around 20 years)
- We would not use this approach for all the plants we have studied in the Kuuku I'yu medicinal plants project – other protection mechanisms may be more appropriate for some plants

Acknowledgements

- Chuulangun Aboriginal Corporation Claudie, Moreton and Nelson families
- Dr Nick Smith
- Dr Bradley Simpson, Dr Chi Ndi, Dr Jiping Wang, Prof Ross McKinnon, A/Prof Cobus Gerber
- Quality Use of Medicines and Pharmacy Research Centre, UniSA
- UniSA Ventures





National Health and Medical Research Council