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## COMMUNITY ECONOMIC DEVELOPMENT

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### IN PATENTING TRADITIONAL KNOWLEDGE:

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# A CASE STUDY OF THE MUDJALA TK PROJECT IN THE KIMBERLEY REGION OF WESTERN AUSTRALIA

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*by Virginia Marshall, Terri Janke and Anthony Watson*

#### INTRODUCTION

The Court observed during an intellectual property matter in the Supreme Court of the United States that, ‘he who seeks a better mouse trap today has a long path to tread before reaching the Patent Office’.<sup>1</sup> Equally the path to realising patent registration for the Nyikina Mangala peoples has, and continues to be, a journey of longstanding patience and commitment to realise a marketable traditional remedy, and in due course, possibly a pharmaceutical product. The Nyikina Mangala community and its project team have pioneered the way to understand how to balance sustainable development, maintain rights in traditional knowledge (‘TK’) use, and develop meaningful project partnerships under the patent system.

Historically, the framework of patent laws has been concerned with the creation of a monopoly over an invention; by patent registration so as to ensure the legal enforcement of the patent holder’s exclusive property rights. For Aboriginal and Torres Strait Islander communities of Australia the conceptualisation of the patent system is far removed from how Indigenous communal laws protect community property rights. Consequently, Indigenous peoples depend on the adoption of national laws to protect Indigenous TK for the commercialisation of discoveries and innovations.<sup>2</sup> There remains ‘unfinished business’ in the legislative and policy regimes of Australian intellectual property.

The primary advantage in the granting of a patent is the economic potential for practical outcomes in community self-determination, whereby unique opportunities exist for Indigenous communities to control the commercialisation process, engage in culturally appropriate community training in scientific methodologies and provide for sustainable development projects on ‘country’.<sup>3</sup> As Indigenous traditional medicine meets the health needs for 80 per cent of developing countries, the demand for Indigenous medicines is the keystone for the health

needs of the global community.<sup>4</sup> Australia has a unique opportunity to lead the world in ensuring that the commercialisation of Indigenous TK is collectively managed and developed by the respective Indigenous communities who hold the TK *and* the patent right.

#### FROM FISHING CROCS TO PATENT INNOVATION

The background to this case study begins in 1986 when Senior Nyikina Mangala Lawman, John Watson, had half his finger bitten off by a crocodile when hunting on his ‘country’.<sup>5</sup> Some hours away from medical assistance he required an urgent response. Mr Watson used the bark of the ‘nyardoo majala’ tree to stem the pain before making the long journey to the Derby hospital. The nyardoo majala tree has always been known to the Nyikina Mangala community in this region. It holds cultural significance, both in the healing powers and pain control relief it provides and in the creation story of the Fitzroy River<sup>6</sup>.

The Nyikina Mangala Elders appointed former Kimberley Land Council administrator, Paul Marshall, as their agent to explore the commercialisation potential of the majala plant; who in due course arranged a meeting with Professor Ron Quinn, a Brisbane-based scientist with Griffith University,<sup>7</sup> and leader in natural product discovery and commercialisation. Subsequent negotiations led to a ground-breaking Australian Research and Development partnership between Griffith University and Jarlmadangah Burru Aboriginal Corporation (‘Jarlmadangah Burru’) on the basis of a pre-negotiation agreement.<sup>8</sup> Between 1987 and 1997 an intensive period of scientific research ensued to isolate and identify the active analgesic compounds in the nyardoo majala; identification is required to prove they were a ‘novel’ class of compounds.

During the next decade further discussions by the community and the university were centred upon gathering resources to prepare and lodge the Australian

patent application; which included engaging pro bono assistance, taking community instructions and preparing scientific research on analgesic activity to satisfy the patent application under the *Patents Act 1990* (Cth) (the '*Patents Act*'). Jarlmadangah Burru's first Australian patent application was lodged in 2003.<sup>9</sup> The critical issues during this stage were to access the limited pockets of funding in order to sustain the research and development of the project; and to incorporate the advances in extraction technology. It was recommended that to achieve an efficient and effective business response and to make timely commercialisation decisions on behalf Jarlmadangah Burru an incorporated entity was necessary.<sup>10</sup> The company JJLab<sup>11</sup> became operational in 2006 in order to hold the intellectual property assets and respond to commercial matters.

In 2008 Jarlmadangah Burru and Griffith University licenced the intellectual property technology to Avexis, so as to develop commercialisation opportunities; these arrangements were in place for approximately a year. The licensing with Avexis took place as the Global Financial Crisis impacted on international industry and investment funds for biotech all but dried up. The costs for an Aboriginal community seeking commercialisation of traditional plants under the patents system are expensive to commence and progressively more costly to market.

Jarlmadangah Burru and Griffith University were certified as co-owners of the Indigenous biotechnology patent.<sup>12</sup> Additional patent registrations for the mudjala patent have been successfully granted in Australia,<sup>13</sup> Japan,<sup>14</sup> India,<sup>15</sup> New Zealand<sup>16</sup> and the United States of America.<sup>17</sup> A patent application in Europe was applied for, however the examination period of this patent system is extremely difficult to undertake because of internal bureaucratic process and outrageous costs in translating the supporting material for the patent application.

On reflection, bringing the attention of the traditional Aboriginal medicine plant to Griffith University did result, over time, in the 'hand-shake' partnership being translated into a formalised collaborative research partnership with Jarlmadangah Burru. IP Australia now recognises the 'Mudjala TK Project' as the leading Indigenous owned medicine patent project in Australia.<sup>18</sup>

Realistically, the years spent in developing an initial dialogue with Griffith University and the formal discussions and negotiation to structure the intellectual property assets between the university and the Jarlmadangah Burru community has been particularly

intensive for all parties. The most challenging aspects in developing the patent project was to establish a legal agreement for the commercial partnership, undertaking the scientific research to support the patent application, securing ongoing project funding from government and private sources and to coordinate and manage the lengthy patent application and examination stages. The considerable fees in making patent applications and the annual renewal of patents create an economic burden on Aboriginal communities, which is a disincentive to commercialisation.

## PATENT RIGHTS AND INDIGENOUS TK: THE PROCESS IN PATENT REGISTRATION

Patents are the oldest western form of intellectual property.<sup>19</sup> In Australia, before the federation of states, each colony had separate patent legislation.<sup>20</sup> In October 1990 the *Patents Act* commenced; patent case law was mainly based on the *Patents Act 1952* (Cth).<sup>21</sup> A grant of patent rights is focussed upon the registration of the invention; s 29 of the *Patents Act* defines a patent as a 'standard' or 'innovation patent'.<sup>22</sup> The evolution of the patent process has only emerged in recent times to consider the nature of Indigenous TK.

A provisional patent application for registration must meet the requirements under the tests of novelty,<sup>23</sup> inventive<sup>24</sup> and innovative<sup>25</sup> steps. If the registration test is successful the applicant then requests an examination of the patent;<sup>26</sup> the examination process is compared against 'criteria'<sup>27</sup> and 'specifications'<sup>28</sup> to accept the patent.<sup>29</sup> A patent that is granted is then filed with IP Australia in Canberra; the Commissioner must publish 'certain information'<sup>30</sup> about the patent granted for public inspection. Where no opposition is brought against a grant of the standard patent a final approval is made. Generally, the date of filing of the 'complete specifications in the patent application'<sup>31</sup> constitutes when the period of exploitation commences. The patent owner or joint owners have 'exclusive rights'<sup>32</sup> to undertake commercial use.

The various stages of the patent process in Australia, from initiating the TK application under the *Patents Act* to the granting of a patent, takes approximately two years. However, the notion of patenting Indigenous TK is a contentious issue for many Aboriginal communities because patent legislation requires exposing traditional community knowledge or even secrets under Aboriginal law and communicating traditional plant use in the public domain.<sup>33</sup> There is always a danger in that TK is not suitable to be known by others outside the Aboriginal

community group or used widely for commercial projects or products. The concerns held by many Indigenous TK holders are that their traditional property will be inappropriately exploited by others and that the respective Aboriginal community will not receive recognition or financial remuneration for their TK.

### THE ISSUE OF TK SECRET USE

Undertaking the commercialisation of Aboriginal community TK of plant or other resources has to be carefully considered by the community at large because the patent system requires a long term commitment to prepare the written material for a patent application, endure the examination and opposition stages and to motivate funding partners to assist with fieldwork or clinical trials and market the final TK product. The protection of Aboriginal community 'sacred-secrets' or TK that is deemed unsuitable for other persons not of the community is an important discussion to have in the pre-patent process. Quite simply it may not be appropriate for Indigenous peoples to patent because their TK is in the public domain and therefore has the potential for exploitation and commercialisation by non-Indigenous individuals or entities.

The World Intellectual Property Organization ('WIPO') defines 'secret' as 'something that is kept from the knowledge of others or shared only with those concerned'.<sup>34</sup> 'Sacred-secret' TK and cultural expressions 'have a secret or sacred significance according to the customary law and practices of their traditional owners'.<sup>35</sup> However under the *Patents Act* 'secret use' does not define or include TK, either as an integral stage in the qualifying 'novelty' stage of the patent or by the recognition of *sui generis*<sup>36</sup> in terms of a non-patent TK holder in either the use of a plant or resource.

Whilst the grant of a patent confers an exclusive property right to exploit the TK invention, for a number of reasons there are pitfalls to consider when sharing TK with the world at large. A 'secret use' under the *Patents Act* is not for the purposes of:

reasonable trial or experiment; in the course of confidential disclosure, other than the purpose of trade or commerce or in the disclosure of an invention to the Commonwealth, State or Territory.<sup>37</sup>

If, a 'secret use' of Aboriginal medicinal plants or plant properties was placed on the Australian Register<sup>38</sup> of the *Patents Act*, it requires a record of the particulars of the patent. In many cases, the information on record may be culturally inappropriate to declare. The protection of TK

is often incompatible with Western legislative regimes; whereby an infringement of Indigenous TK by others, including community members, may offer unsatisfactory relief.<sup>39</sup>

### LIFE AFTER THE PATENT IS APPROVED

Aboriginal laws have long preceded the common law and statutory frameworks. The purpose in the original drafting of the *Statute of Monopolies 1623* in England was to grant the right to monopolise patents for commercial reward.<sup>40</sup> In Australia, at the time of federation the *Patents, Designs, and Trade Marks Act 1883* (UK) was in force. Around this time in 1872, David Unaipon, a Ngarrindjeri man, was born at the Point McLeay Mission in South Australia. In 1909 Unaipon patented an improved sheep shearing tool and other inventions such as a centrifugal motor, a multi-radial wheel, and a mechanical propulsion device.<sup>41</sup> This indicates that the value of patent registration was recognised as paramount to protecting an inventor's right, both for Aboriginal and non-Aboriginal people.

Undoubtedly, the financial issues of attracting private venture capital and significant investment in the development stages after the patent is granted have the ability to impede commercialisation. The Aboriginal community involvement during the patent discussions and patenting process must be one of informed and consistent communication and of ongoing consultation.

The practical benefits gained from funding<sup>42</sup> the Jarlmadangah Burru community is that by participating in harvesting and monitoring trials and natural resource and sustainable wild harvest management, the Nyikina Mangala Rangers have been trained in vegetation assessment and mapping of mudjula. For Aboriginal communities the opportunity to wild harvest or, cultivate and supply, the plant material required for the supply chain is one way of ensuring Access and Benefit Sharing<sup>43</sup> arrangements.

Article 31 of the *United Nations Declaration on the Rights of Indigenous Peoples* asserts Indigenous rights to own and control the intellectual property of the TK; whereby the exercise of such rights should allow Indigenous people to enter into agreements with research institutions, and commercial partners, so that they can enjoy benefits.<sup>44</sup> It cannot be understated that agreements made between Aboriginal communities and third parties must be diligent to craft the provisions and schedules to recognise and protect TK and the commercial and non-commercial benefits which should flow to the Aboriginal patent holders.

## CONCLUSION

This case study shows that there is scope for mutually agreed benefits and sharing of intellectual property to be included as part of the biotechnology model. Here, the bringing together of the natural product expertise of Professor Ron Quinn with Jarlmadangah Burru TK, supported by a dedicated pro bono project team, has led to a remarkable partnership. The development of a novel pain-killing medicine from traditional Aboriginal medicine is also significant as a leading case study for other Indigenous peoples. Whilst yet to progress 'mudjula' to a saleable remedy with royalty returns, there is a strong intention to develop a community supply chain that reinforces a range of lasting benefits for the remote Jarlmadangah Burru community and actualised self-determination. However, the patent process is not the only avenue in the sharing of TK. Although patents legislation needs to address a more inclusive recognition of TK, there is an imperative to ensure governments and industry provide funding, as well as philanthropic investment, into the research and development of Aboriginal controlled TK.

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- 1 Edmund Kitch, 'The Nature and Function of the Patent System' in Arti Rai (ed) *Intellectual Property and Biotechnology* (Edward Elgar, 2011) 22. Citing the case *Graham v John Deere Co* (1966) 383 US 1 19 in Edmund Kitch and Harvey Perlman, *Legal Regulation of the Competitive Process* (Foundation Press, 1986).
- 2 Patricia Marin, *Providing Protection for Plant Genetic Resources: Patents, Sui Generis Systems, and Biopartnerships* (Kluwer Law International, 2002) 183.
- 3 The meaning of 'country' is the traditional lands and waters which connect the Aboriginal person to community in kinship and underpin the obligations to protect and care for 'country'.
- 4 Matthias Leistner, 'Analysis of different areas of Indigenous resources: Traditional Knowledge' in Silke von Lewinski (ed) *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore* (Kluwer Law International, 2004) 50.
- 5 Janelle Mills, 'Aborigine, scientist find pain relief in marjara tree', *Courier Mail* (online), 21 October 2008 <<http://www.couriermail.com.au/news/queensland/native-tree-bark-eases-pain/story-e6freoof-111117814741>>.
- 6 This means freshwater mangrove in Nyikina language.
- 7 The Eskitis Institute for Cell and Molecular Therapies, Griffith University, has a formal agreement with Jarlmadangah Burru Aboriginal Corporation.
- 8 The Pre-Negotiation Secrecy Agreement entered into in 1987.
- 9 The patent application in Australia was lodged in 2003. From 2004 Australian lawyer Mark Allen provided pro bono legal assistance for the Mudjula project; in 2010 Indigenous lawyer Virginia Marshall joined with Mark Allen to provide continuing pro bono support.
- 10 JJLab Pty Ltd was incorporated to enable the timely response to commercial undertakings.
- 11 JJLab was necessary to hold the patents and to undertake third party commercial opportunities in a timely manner.
- 12 Geoff Vivian, *Fitzroy Valley Aboriginal community patents pain-killing natural medicine* (17 August 2011) Science WA <<http://www.sciencewa.net.au/3585.html>>.
- 13 Patent granted Application number 2004293125 and PCT/AU2004/001660. PCT is 'Patent Cooperation Treaty'. Australia is a party to this Treaty which provides Treaty parties the ability to obtain a patent protection for invention in countries other than Australia.
- 14 Patent granted Application number 2006-540096.
- 15 Patent granted Application number 25290.
- 16 Patent granted Application number 547377.
- 17 Patent granted Application number 7618946.
- 18 IP Australia, *Nanga Mai Arung Dream Shield: A guide to protecting designs, brands and inventions for Aboriginal and Torres Strait Islanders* (2010) 31 <<http://www.ipaustralia.gov.au/pdfs/dreamshield-publication.pdf>>.
- 19 Rocque Reynolds, Natalie Stoianoff, Angela Adrian and Alpana Roy, *Intellectual Property: Texts and Essential Cases* (Federation Press, 2012) 279.
- 20 Ibid 281.
- 21 Ibid 282.
- 22 S 67 states that 'the term of a standard patent is 20 years from the date of the patent'; s 68 states that an 'innovation patent is for a term of 8 years'; s 70 allows for patents owners to apply for an extra five years protection for pharmaceutical patents.
- 23 *Patents Act 1990* (Cth) s 7(1).
- 24 Ibid s 7(2) & (3). The inventive step for the mudjula patent was detailed in the specifications as 'novel compounds'.
- 25 Ibid s 7(4), (5) and (6).
- 26 Ibid s 44.
- 27 Ibid s 18.
- 28 Ibid s 40.
- 29 Ibid. S 49 states 'the Commissioner, if satisfied on the balance of probabilities, that the specifications for a standard patent are met that the Commissioner must accept the patent request'.
- 30 Ibid s 53, 54 and 55. Opposition to a grant of a standard patent may be made (within 3 months of publication) on limited grounds under s 59 of *Patents Act 1990* (Cth).
- 31 Ibid s 65; 'is the date when the patent runs'.
- 32 Ibid s 13.
- 33 Information on patents and patent applications are made public on the 'Australian Official Journal of Patents' at the Australian Patent Office.
- 34 WIPO, 'secret use' <<http://www.wipo.int/tk/en/resources/glossary.html#45>>. See Black's Law Dictionary.
- 35 Ibid. See 'secret use' described in the 2002 Pacific Regional Framework for the Protection of Traditional Knowledge and Expressions of Culture Part I (4).
- 36 Patricia L C Marin, *Providing Protection for Plant Genetic Resources: Patents, Sui Generis Systems and Biopartnerships* (Kluwer Law International, 2002) ch 5. Discussed in developing countries, a *sui generis* intellectual property system, in view of Art 27(3)(b) of the Trade-Related Aspects of Intellectual Property Rights ('TRIPs') Agreement, would allow international recognition and protection of TK. However, the recognition

under Australian law of *sui generis* does not include any economic value of the resource, plant or in the TK itself.

37 *Patents Act 1990* (Cth) s 9.

38 *Ibid* s 186.

39 *Ibid* s 122.

40 Colin Bodkin, *Patent Law in Australia* (Law Book Co, 2008) 2-3.

41 Reserve Bank <[www.rba.gov.au/biography-david-unaipon.html](http://www.rba.gov.au/biography-david-unaipon.html)>.

42 Streams of government funding provide significant assistance in community training and education to ensure that the Nyikina Mangala Rangers and broader community are able to take leadership roles in the future marketing of 'mudjula'.

43 Access and Benefit Sharing is defined under the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*—'an international agreement which aims at sharing the benefits arising from the utilisation of genetic resources in a fair and equitable way' and 'was adopted by the Conference of the Parties to the Convention on Biological Diversity on 29 October 2010 in Nagoya, Japan'. See <<http://www.cbd.int/abs/>>.

44 See TK discussion page 32 of the United Nations Global Compact <[http://www.unglobalcompact.org/docs/issues\\_doc/human\\_rights/UNDRIP\\_Business\\_Reference\\_Guide.pdf](http://www.unglobalcompact.org/docs/issues_doc/human_rights/UNDRIP_Business_Reference_Guide.pdf)>.

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