

## Digital Rights Management and the Traditional Knowledge Database

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### Abstract

Patenting traditional knowledge (TK) without the consent of right-holders is a contentious issue. There are a number of proposals that seek to defeat Western patents of TK by using a database to defeat novelty. Legal protection of these databases, particularly in the USA, appears to be a concern of many potential TK right-holders. There are provisions in international and US law that can protect a TK database from infringers.

**Key Words:** Traditional Knowledge, Database, Legal Protection.

### Introduction

Many countries that are rich in genetic resources and traditional knowledge (TK) are concerned that their resources are being patented without their consent. India has been instrumental in gathering momentum for a database (to be used only by national patent granting authorities) of TK to defeat patent applications for lack of novelty. However, there are concerns that the database could facilitate rather than hinder patents. The question arises: what if non-authorized users had access to this information? How can the rights of the authors be protected?

This paper will address this concern in particular. But before moving on, some attention should be paid to the problems the database was designed to overcome. India entered the fray after a controversy over a patent for a substance obtained from Neem. Texts dating back two millennia stated that Neem could be used as an insecticide. W.R. Grace & Co. filed a patent application covering a hydrophobic extract of Neem for use as an insecticide and fungicide.<sup>1</sup> The patent detailed a method to stabilize the active agent, a chemical called Azadirachtin, and also covered the stabilized form of the substance.<sup>2</sup> After first granting the patent, the European Patent Organization (EPO), rejected it for lack of novelty. Article 52(1) of the Munich Convention states that patents are granted on the basis of novelty, inventive step, and suitability of industrial application. Novelty is determined in relation to the state of the art, which according to Article 54(2) means "...everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application." These provisions clearly protect TK, the bulk of which is not written.

The same is not true of patent practice in the USA, where the examination relies upon printed materials for inventions made outside of the country. According to 35 U.S.C. §102 a person shall be entitled to a patent unless: "(a) the invention was known or used by others in this country, or patented or described in a printed publication in

this or foreign country...” After the Neem controversy, India - along with several other countries with extensive TK traditions - recognized the need for a central database that would record TK that was often only known in oral form. This initiative was stimulated by a meeting of the South Asian Association for Regional Cooperation (SAARC), and it was envisaged that every country in the organization would prepare a TK database. While the SAARC would fund the infrastructure, each country would fund the costs of the work itself. Already in 2001 India had developed a system of classifying TK resources that was adopted by the International Patent Classification (IPC), which agreed to include about 200 sub groups of drugs derived from medicinal plants from India.<sup>3</sup> The fact that this is a regional effort is particularly significant, as TK may not follow national boundaries.

In late 2005 the EPO was due to sign an agreement with the National Institute of Science Communication and Information Resources (NISCIR) in India so that the EPO could search a database of Indian traditional medicine. This would allow patent agencies to search the database for prior art.<sup>4</sup> If the patent claim appeared in the prior art, it would defeat a patent application on the basis of novelty. The NISCIR is negotiating with patent offices in the US, UK, Sweden, and Japan, and the NISCIR hopes that in the future there will be an international legal mechanism established by WIPO to protect TK.<sup>5</sup> Such a wide ranging means of protecting TK, however, would take a considerable amount of time to establish. Until then another method must be found to protect TK right holders.

At first glance the database appears difficult to put into practice. Given that a range of different specialties would have to be represented, it is no easy task. It would also have to be regularly funded in order to be up to date. Perhaps even more ominous, some have suggested that the database could be used to further piracy. The Traditional Knowledge Digital Library Task Force found that of the 4,896 references on 90 medicinal plants in the United States Patent and Trademark Office database, 80 per cent of the references pertained to just seven medicinal plants of Indian origin. In other words, nearly 4,000 patents or patent applications are based on the medicinal properties of plants that were already known. The Task Force studied the patents and found that 360 of the 762 patents on medicinal plants that were granted by the USPTO could easily be categorized as traditional.<sup>6</sup> In an age where the reproduction and dissemination of electronic material is so simple, the database would be a very tempting target for misuse.

There have been calls to stop the project, as many authors did not want to participate in a venture that could be damaging to their communities.<sup>7</sup> There is also a general reticence of some to commit an oral tradition to writing, as local communities worry that they lose control of their sacred or cultural property. Clearly a major issue in the debate is the level of protection of the proposed database. A printed source is not easy to update, and it is very difficult to control access. A digital database can be updated as needed and access can be restricted. However, no method of technological protection can ever be assumed to be secure. Assuming the database was “hacked” and used to look for patentable material, the resulting patent application could be drafted so that the original inspiration could be obscured. It is also clear that a major focus of the database is for the US patent authorities to use to defeat the novelty of proposed patents. The main question that arises is this: assuming that the TK database, which uses technical measures to protect it, is used by a non-authorized user, what laws would apply? What sanctions would be available and finally, how effective would these be in protecting the database?

Of particular importance here is the nature of the TK database. At first the compilers will put materials on the database that have already been printed, although perhaps originally in a number of non-European languages. Later original materials will be collected from a number of sources. As is the case with much TK, it may be controlled by members of the community who in turn may change the TK over time. There can thus be older static elements as

well as newer elements attributable to an individual. A member of a “traditional” community could enjoy copyright as an author on these new additions according to western standards, although under traditional law it may be the community as a whole that retains these rights. As has been noted before, Western concepts of intellectual property rights do not easily accommodate collective forms of ownership. According to the US copyright laws, a translator and the final organizer of the work as a whole would also clearly have copyright. Without going into further detail about the conflict between “indigenous” and Western laws, the closest parallel to the TK database would be something like an encyclopedia.

### **International Law**

Article 2(5) of the Berne Convention deals specifically with collections of literary and artistic works such as encyclopedias and anthologies: ... “which, by reason of the selection and arrangements of their contents, constitute intellectual creations that shall be protected as such, without prejudice in each of the works forming part of such collections.” In the case of the TK database all authors of the work, including translator and final arranger, should fall under copyright protection. The definition of “work” in the convention is clear in that it must have a degree of originality. The TRIPS Agreement, which came into force on January 1 1995, more specifically deals with the issue of material on a database held in digital form. Article 10(2) states that: “Compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself.” TRIPS article 10(2) is largely mirrored in article 5 of the WIPO copyright treaty which came into force in March 2002.

Besides the subject matter itself, international agreements also provide for the effective use of technological measures of protection. Article 11 of the WIPO Copyright Treaty states that contracting parties must: “...provide adequate legal protection and effective legal remedies against the circumvention of effective technological measures that are used by authors...” If a technological measure were employed to protect a work, then a signatory country must prohibit any facilitation of circumvention measures as well as restrict the production, distribution, and making available of protected material. As somewhat of an aside both India and the USA are signatories of the Berne Convention, TRIPS, and the WIPO copyright treaty. Thus there is a clear framework of international law to protect the TK database.

### **Protection of a TK database in the USA**

The first issue to address is if the TK database, even if written by a non-American, would be covered by American law. According to the US Copyright Act of 1976, section 104, unpublished works are subject of protection regardless of nationality, and published works are protected if they were first published in a country that is a “treaty party”. In any case if the work is published in a non treaty country and published 30 days after in the US, it is deemed to be published in America. The next step is the form of the database itself, is it creative enough?

If a work is not creative, it is not protected. The best example are phone books which rely upon simple alphabetical arrangement of data. This kind of information does not fall under copyright, as was made clear in the case *Feist v Rural Telephone Service Co.*, 111 S. Ct. 1282 (1991). Supreme Court Justice O’Connor stated that originality was not a stringent standard, and that facts did not have to be presented in a novel or surprising way. Yet a mechanical or routine method of arrangement does not satisfy the statute. There was no “sweat of the brow” test

for protection, but one based on a low hurdle of originality. The court noted in the Feist case that the vast majority of compilations would pass the originality test. It is almost certain that a proposed TK database would not be mechanical but would reflect the creativity of the authors.

The next question to address is what kind of protection can be offered to a database. The European Union has passed legislation to protect the information contained in a database. Called the Database Directive, it came into force on 1 January 1998. This directive only protects databases produced in the EU. An un-copyrightable US database could be reproduced and marketed in Europe and there would be no legal means to stop infringement. While there has been discussion in the USA about similar measures, to date no similar law to the Database Directive has been enacted. Copyright law does not protect the data itself. According to 17 US Code 101 a compilation is "...a collection and assembling of preexisting materials or of data that are selected in such a way that the resulting work as a whole constitutes an original work of authorship." The creative element is protected, that is the arrangement or selection of the data. In the case of a translation of oral traditions, such as the proposed TK database, several issues arise. Perhaps only a fragment of information, such as the fact that a plant like Neem could be used as an insecticide, would be useful for obtaining a patent. The artistic or literary aspects of the text would not be required. Yet in order to distribute the information, the texts - or substantial parts of them - would have to be copied. This act would leave the infringer liable to copyright infringement unless the creative element of the information was removed or "re-tooled." The latter scenario does not appear to be likely.

## **Fair Use**

According to US law, copyright law covers the right to make as well as distribute copies of the work. This includes the right to prepare derivative works. An infringer who takes material from a copyrighted database would make and distribute copies, which is prohibited. Section 107 outlines provisions that limit these rights somewhat by providing for "fair use". At first this doctrine may appear to be something of a hidden bomb that defeats the rights of copyright owners. It might be particularly threatening in the case of a TK database as there are no doubt many academic uses for it that would not involve any intention to infringe. On closer inspection the fair use doctrine is quite limited in scope. This section specifically mentions scholarship and research as within the scope of fair use. The purpose and character of the use will be considered. Thus the commercial nature of research leading to a patent would be considered in a different light than academic research. Section 107 also considers the amount and substantiality of the portion used, so that even if access were obtained it would not be possible to reproduce large sections under the fair use doctrine. Even if an academic user gained access to or copies of the database only limited amounts could be used under this provision.

Fair use has been further restricted by recent legislation that allows authors to use methods of Digital Rights Management (DRM) to control how their works are used. The WIPO Copyright Treaty guaranteed rights that were, according to some, not well protected by American law. The Digital Millennium Copyright Act (DMCA) amended title 17 of the United States Code. The DMCA provides stiff penalties for the production and distribution of technology that can circumvent measures taken to protect copyright. According to 17 USC § 1201 there is a distinction between those technological measures that control access and those that protect other rights, including fair use. In order for a user to exercise "other rights," such as fair use, one must first gain access. The law makes the circumvention of technological measures a criminal offence and does not consider the motives for doing so. It would appear that, although fair use doctrine is well established in statute and case law, the DMCA makes this

exception difficult to exploit in practice. The DMCA is purposefully inflexible in order to strengthen technical controls using legal means. It also shifts the enforcement of right holder's interests from penalties for unauthorized infringement to sanctions for unauthorized use. "Given that DRM is only able to channel user conduct into dependably secure behaviors when its architecture is predictable and deterministic, the legal imperatives that guard the technical controls must be equally predictable and deterministic. Just as technical regulation under DRM cannot accommodate the fact-dependant, ex ante flexibility of legal standards, so the accompanying legal regulation of circumvention resists such situation flexibility."<sup>9</sup>

The law in effect allows the copyright holder to write his own law in computer code, and it is no surprise that public access under the fair use doctrine is often not considered. In the case of monopolistic enterprises, where the interoperability of components is an issue, this could be appreciated as anti-competitive. In protecting a TK database, it is unlikely that such public policy issues would be raised. Instead, with strict protection of DRM systems, it makes it more likely that the proposed TK database would receive the support of many communities. However, a question to address at this juncture is whether this is the best way forward. The proposed TK database would cover a vast subject area. Considering increasing amounts of information, some of it perhaps appearing for the first time in written form, it would be of interest to academics such as anthropologists. Aside from a rather altruistic conception of sharing knowledge, specialist academic attention could perform useful functions, such as identifying gaps in the information or even correcting faulty data. The danger remains that if the database were simply produced by a small group of people and used by another select group it would be a self-pollinating system.

One option would be to "code for fair use" by allowing some users - academics for example - to view material for a certain period of time, perform a certain number of searches on the database, or to extract a certain amount of material. The main problem is simple. The program restricting access would by necessity be complicated. It almost certainly would not anticipate the range of needs encountered by "fair use" research. The other option is to appoint a controlling body that would act as a gatekeeper for the database. The unique circumstances of every case could be carefully accessed, and bona fide fair use research could be used to improve subsequent versions of the database. Representatives of the authors could be involved in controlling access by distributing electronic "keys" that would access encrypted work.<sup>10</sup> It would be important to keep a record of the keys, perhaps having them expire after a certain interval of time, and perhaps also recording what kinds of research were conducted with the database. While there would be a lack of anonymity, and casual use would be hindered, such a system would still allow access of a limited sort. This would likely satisfy most contributors to the database.

## **Electronic Theft**

There are also legal provisions to protect copyright even if there is no commercial element involved. In 1994 the court suggested that the current state of the law allowed David LeMacchia, a student at MIT, to facilitate large scale copyright infringement because there was no commercial motive. Reacting to the newly created "LaMacchia loophole", in 1997 the No Electronic Theft Act (NET Act) was passed that established criminal sanctions for copyright infringement. It was specifically aimed at software but applies to other copyrighted work as well. Not surprisingly, it was supported by the software and entertainment industries, and opposed by groups representing scientists and academics. Before the NET Act, it was possible to sue infringers only in a civil action to recover damages. The NET Act establishes that the exchange of copies of copyrighted work is an offence even where the infringer expected to obtain nothing of value. Sentences up to five years in prison are now established, as well as

\$250,000 in fines. However, copying a work with a total retail value over \$1000 and under \$2,500 is a misdemeanor (above that limit it is a felony) and the maximum sentence is one year and a fine of \$100,000.<sup>11</sup> It may be difficult in practice to place a value on any infringement of the TK database, but the law is clearly in place to discourage offending behavior.

## Conclusion

Various nations and groups have fears that their TK is being used by foreign companies in order to secure patent rights. Not only is this knowledge used without permission, it can be used as the basis for non-novel patents. A TK database can demonstrate that a particular use of a substance is not new. It is at the same time a powerful tool for a patent office, and an effective research tool for unauthorized users. For the communities (the authors of the TK) who will provide the information, there is understandably concern that the project could do more harm than good if there were no effective remedies against infringers. In fact, with the calls to stop the project all together, it appears that the effectiveness of laws to protect author's rights is the core concern.

US copyright law, particularly the DMCA, is a powerful tool to protect the database and the rights of the authors who contributed the TK. While traditional copyright law does not protect the knowledge contained in the database itself, there is in effect "back door" protection in that if technological measures are used to protect the database, the law will prohibit circumvention. Even before the DMCA, and now in addition to it, there are provisions that sanction copying materials that fall under the Copyright Act. In both cases it is up to the right holders to enforce their rights. But right holders might want to cooperate with some members of the world community. The database could be improved by drawing upon the potential of academics to improve the quality of information, provided of course that suitable DRM systems are employed to discourage unauthorized use. Whatever the final outcome, it is clear that the problem of how to protect the TK database is a serious one.

While there could be fears that various national governments would not invest the required amount in legal fees to pursue infringers, the *Neem* case demonstrates that this might be a false assumption. The DMCA and to a lesser extent the NET Act are in some ways a reversal of the "usual" trend where less developed countries are encouraged to implement stricter intellectual property laws to encourage outside investment. In this case recent changes in US law may encourage less developed countries to record their intellectual property. The goal of protecting author's rights, and preventing the issuance of non-novel patents, is one that all countries can share.

<sup>1</sup> For a general discussion see Emily Marden, *The Neem Tree Patent: International Conflict over the Commodification of Life*, 22 Boston College International and Comparative Law Review 279 (1999).

<sup>2</sup> U.S. Patent No. 5,281,618 (issued Jan 25 1994).

<sup>3</sup> T.V. Padma, *Digital Library to protect indigenous knowledge*, 10 January 2005,

<http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=1840&language=1>

The scope of the database according to this report is "traditional medicine, foodstuffs, architecture and culture." It appears that the main focus of the database is traditional medicine, so it is quite logical that it would contain information about foodstuffs as well.

<sup>4</sup> "Prior art" is a legal term that refers to all previous inventions in a particular field for which a patent is sought. It is used by patent offices to determine if an invention is unique and non-intuitive enough to qualify for a patent.

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- 6 Devinder Sharma, *Digital Library Another Tool for Biopiracy*, 29 May 2002, <http://www.thehindubusinessline.com/2002/06/12/stories/2002061200120900.htm>
- 7 *Traditional Knowledge Digital Library Seeks to Prevent Biopiracy* <[http://sippi.aaas.org/ipissues/updates/?res\\_id=618](http://sippi.aaas.org/ipissues/updates/?res_id=618)> Source: J. Lancaster, India digitizes age-old wisdom, *The Washington Post*, January 8, 2006, at A22. The article states that the Digital Library would be made available to foreign patent offices “at some point later this year”.
- 8 Nicola Lucchi, *Intellectual Property Rights in Digital Media: A Comparative Analysis of Legal Protection, Technological Measures, and New Business Models under EU and U.S. Law*, 53 *Buffalo Law Review* 1143 (2005).
- 9 Dan L. Burk, *Legal and Technical Standards in Digital Rights Management Technologies* 74 *Fordham Law Review* 537 (2005) 23-58
- 10 Dan L. Burk and Julie E. Cohen, *Fair Use Infrastructure for Copyright Management Systems*, Georgetown University Law Center 2000 Working Paper Series <[http://papers.ssrn.com/paper.taf?abstract\\_id=239731](http://papers.ssrn.com/paper.taf?abstract_id=239731)>
- 11 A summary of the changes can be found at <<http://www.cybercrime.gov/netsum.htm>>