



# **From Traditional Medicines to Modern Drugs: Do Patents Protect Inventions *and* Promote Biopiracy?**

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## *Two questions:*

1. Is traditional knowledge important in drug discovery?
2. Does patent law help drug companies claim possession of traditional knowledge?



# 1. Is TK important in drug discovery?

*Two common responses:*

- *“Yes – definitely – very”*
- *“Maybe in the past, but not any more because the science has advanced and people can make anything in the lab”*



## My answer:

1. TK *is* still important, but not as much – or as little - as some people think.

2. The potential of TK has not been fully explored, but realising that potential is extremely difficult.

*But as scholars you must come up with your own answers on the basis of the evidence you find, your interpretation of that evidence, and your own reasoning.*



## **TK importance likely to be *underestimated* because:**

- (i) As new chemical entities continue to be hard to find, scientists often go back to earlier substance to identify novel properties (e.g. aspirin).
- (ii) The “learning trails” from initial find to a product or class of products are hard to trace. The natural/TK origins of “new” drugs may become forgotten.
- (iii) The modern use may be completely different, leading us to forget where the initial lead came from.
- (iv) Sometimes it’s just too early to tell.



## **TK importance likely to be overestimated because:**

1. People assume that because it was important in the past, it will remain important.
2. “Biopiracy” scares have attracted more attention than is warranted.
3. There is a tendency to be romantic about indigenous peoples and to demonise “big pharma”.



# Traditional Knowledge and Drug Discovery

□ 119 chemicals extracted from higher plants used in medicine (Farnsworth)

□ **74% have the same or related use as medicinal plants from which were derived**

*But does this make traditional knowledge important in future drug discovery?*



## ***Aspirin***

Known for 7,000 years. Used as analgesic & anti-inflammatory agent in Ancient Greece and Rome.

1757 - Rediscovered by Rev Edward Stone, lead by traditional “doctrine of signatures”, & example of quinine.

1828 - Isolated by Buchner.

1853 – chemically modified by Gerhardt. Then by Kraut (1869), *Hoffman, Eichengrün & Dreser (1897) - patents filed in US & UK naming Hoffman as inventor.* Highly successful product for Bayer

Inspired development of whole class of drugs: the NSAIDs – eg paracetamol, ibuprofen

Mode of action discovered by John Vane, 1971

Continuing discoveries relating to aspirin, some patented





## ***Curare - a muscle relaxant used in surgery***

Arrow poison used in South America – causes asphyxiation

1812 – Brodie shows curare's *transient* effect on respiration

1860s – Bernard and student show curare doesn't affect heart, and identify site of action.

1930s – Dale and colleagues use curare as research tool to prove chemicals channel messages to brain; radically enhances our understanding of brain function. *Eventually leads to many spin-off chemicals including Prozac.*

1942 – Successfully tested in surgery. Modified version developed later.



That's then .....

.... But what about now?



“Natural products play a **dominant role** in the discovery of leads for the development of drugs for the treatment of human diseases.”

Hemoxin (sickle cell anaemic treatment): “a mix of plants that came from native healer information and thus can be classified as a ‘true ethnobotanical preparation’.”

Cragg & Newman, *Journal of Natural Products*, 2007



## ***Artemesinin***

Produced by *Artemesia annua* (wormwood)

4<sup>th</sup> Century - Antimalarial activity recorded by Ge Hong

1960s - Chinese military tested medicinal plants

1972 - substance found in leaves of the *Artemisia annua* plant

Modified artemesinin in combination with other products now most effective antimalarial

Mode of action not definitely established. But numerous methods for converting, extracting, & making analogues have been patented



**2. Does patent law help drug companies claim possession of traditional knowledge?**



Since early 1990s, patents relating to traditional knowledge & plants used by them have increased in absolute numbers & as proportion of all patents.

Since 1976, US PTO has issued 255 patents based on properties of neem tree, 580 based on those of turmeric.

D Marinova & M Raven, *Journal of Economic Surveys*, 2006



# How *could* traditional knowledge form the basic subject matter of a patented invention?

- 1 The invention is an inventive step beyond the TK. Therefore there is nothing wrong
- 2 The patent was granted in error - patent examiners cannot possibly have access to *all* of the prior art, so mistakes will happen
- 3 The patent was granted legally despite its similarity to the TK. But undocumented *foreign* traditional knowledge is inadmissible as novelty-destroying prior art (as in USA)
- 4 Patent law gives rights to those who can translate ritual knowledge into “the language of science”, whether or not this translation requires much inventive input, or that any new thing is actually created



## Lord Hoffmann in Merrell Dow v Norton (HL, 1996)

“The Amazonian Indians have known for centuries that cinchona bark can be used to treat malarial and other fevers. They used it in the form of powdered bark. In 1820, French scientists discovered that the active ingredient, an alkaloid called quinine, could be extracted and used more effectively in the form of sulphate of quinine. In 1944, the structure of the alkaloid molecule ( $C^{20} H^{24} N^2 O^2$ ) was discovered. This meant that the substance could be synthesised.”





“Does the Indian know about quinine? My Lords, under the description of a quality of the bark which makes it useful for treating fevers, he obviously does. I do not think it matters that he chooses to label it in animistic rather than chemical terms. He knows that the bark has a quality which makes it good for fever & that is one description of quinine.”



“On the other hand, in a different context, the Amazonian Indian would not know about quinine. If shown pills of quinine sulphate, he would not associate them with the cinchona bark. He does not know quinine under the description of a substance in the form of pills and he certainly would not know about the artificially synthesised alkaloid...”



“The quinine example shows that there are descriptions under which something may in a relevant sense be known without anyone being aware of its chemical composition or even that it has an identifiable molecular structure. This proposition is unaffected by whether the substance is natural or artificial... *Do the same principles apply in the law of patents? Or does patent law have a specialised epistemology of its own?*”



## “Specialised epistemology” ....?

The counsel for the patent holders argued that to show anticipation by description, the anticipation must be provided in the language of chemistry:

*“Mr Thorley says that for a substance to be known so as to be part of the state of the art ..., it must be known (or be readily capable of being known) by its chemical composition. No other description will do.”*

***Lord Hoffmann rejected this argument.***



*Consequently:* You can patent something old & previously used and/or made available to the public if it wasn't known about under any enabling form of description. Otherwise you cannot: patent law does *not* have its own epistemology.



## Discussion

This suggests that mere translation of TK into scientific language is unlikely to be sufficient. *But:*

- Other jurisdictions may not take Hoffman's view. Note that German and US courts took a different position on the patentability of this invention.
- Even if they do, does this make TK safe from the biopirates? How far should the law deal with biopiracy anyway?

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