

**Conference on Intellectual Property and Public Policy Issues
Geneva, July 13 & 14, 2009**



**Promoting Access to
Medicines through
Balancing Patent Rights
& Responsibilities for
Traditional Medicines**

Geneva, July 14, 2009

**V K Gupta, Chairman TKDL Task Force ,
Council of Scientific and Industrial Research, Rafi Marg, New Delh;
E-mail: vkg@csir.res.in**

BALANCING PATENT RIGHTS & RESPONSIBILITIES FOR TRADITIONAL MEDICINES

- **Enhancing quality of Examination**
 - **Prior Art**
 - **International Patent Classification Reforms**
- **Harmonizing Traditional & Modern Medicine**

BALANCING PATENT RIGHTS & RESPONSIBILITIES FOR TRADITIONAL MEDICINES

- **Appropriate regulatory measures for Traditional Medicines**
- **Bolar Provisions**
- **Doha Declaration on TRIPS & Public Health**
- **FTAs & Data Exclusivity**

TKDL

OBJECTIVES AND TARGET AUDIENCE



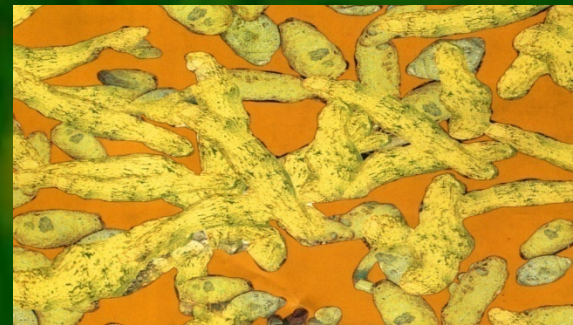
- Prevent Misappropriation of Indian Traditional Knowledge
 - Break Format & Language barriers
- For International Patent Offices only
- Multilingual (French, German, Japanese, English & Spanish)
- Creating new Intellectual Property for promoting Access to Medicines

PROTECTING TRADITIONAL KNOWLEDGE

India

- Turmeric
- Neem
- Basmati

TKDL - TKRC - IPC



Extent of Misappropriation

(Ayurveda, Unani & Siddha)

Study Carried Out in March 2000

4896 references on 90 medicinal plants in USPTO patent databases

80% of references on seven medicinal plants of Indian Origin.

Kumari, Mustaka, Tamraparna, Garjara, Atasi, Jambira, Kharbuza

Almost 50% of patents linked to traditional medicine

STUDIES ON PATENTS ON MEDICINAL PLANTS

- **March 2003** : **15000**
- **December 2005** : **35587**
- **December 2008** : **85000**
- **Medicinal Plant Patents / Year** : **5000**
- **Possible Patents concerning
Indian Plants / Year** : **4000**
- **Possible Patents on Indian
system of Medicine
on yearly basis** : **2000**

International Patent Classification Reform for Traditional Medicinal Knowledge

- **Till 2005 IPC had only one subgroup concerning medical plants**
- **India submitted a proposal on inclusion of Traditional Knowledge at International Patent classification Union in Feb. 2001**

International Patent Classification Reform for Traditional Medicinal Knowledge

- **Five nation taskforce recommended inclusion of 200 sub groups A61K 36/00 for medicinal plants and enhanced IPC implemented in 2005**
- **Need for inclusion of additional 2000 subgroups on Traditional Medicinal knowledge. Indian Traditional Knowledge Resource Classification (TKRC) has 30000 sub groups**

(११८६) गुडूच्यादि काशः
(बं० से० । मसू० त्रि०)
गुडूची मधुकं रास्ना पञ्चमूलं कनिष्ठकम् ।
बन्दनं काशमर्थफलं बलामूलं विकङ्कतम् ॥
पाककाले मसूर्यान्तु वातजायां प्रयोजयेत् ॥

The
United

United States Pat

rights to the person(s) having title
right to exclude others from mak-
ing for sale, or selling the inven-
tion without the United States of Am-
the invention into the Un-
for the term set forth by
ment of maintenance fee

Application was filed prior
term of this patent is
years from the date of
twenty years from the
date of the applica-
any extension.

Application was filed on or
this patent is twen-
te, subject to any
application contain-
earlier filed appli-
U.S.C. 120, 1
is twenty y
which the earliest applica-
any statutory extensions.

Las P. Ebd

United States Patent and Trademark

nda Moo

Key Attributes of TKDL

BP/70

English

Title of Traditional Knowledge

English

Knowledge Known Since

Guducyadi Kvatha(14)

100 years

TKRC CODE : A01A-1/1512, A01A-1/1592, A01A-1/1789, A01A-1/1815, A01A-1/1824, A01A-1/1966, A01A-1/1988, A01A-1/2039, A01A-1/670, A01A-1/920, A01A-3/19, A01D-19/01

IPCCode : A61K35/78,A61K9/08,A61P31/12

DETAILS OF PROCESS / FORMULATION :

1.Guducyadi Kvatha(14) is a therapeutic single/compound formulation consisting of useful parts of following ingredient(s)Tinospora cordifolia (Guduci), Glycyrrhiza glabra (Yastimadhu, Klitaka (Substitute)), Pluchea lanceolata (Rasna), Desmodium gangeticum (Salaparni), Uraria picta (Prasniparni), Solanum xanthocarpum (Kantakari, Laksamana (Substitute drugs) (Sveta)), Solanum indicum (Brahti), Tribulus terrestris (Goksura), Pterocarpus santalinus (Rakta candana), Gmelina arborea (Gambhari), Sida cordifolia (Bala), Solanum xanthocarpum (Kantakari, Laksamana (Substitute drugs) (Sveta))

2. Therapeutic composition/formulation is mentioned below :

English

1	<i>Tinospora cordifolia</i> (Guduci)	(Stem)	1	Part
2	<i>Glycyrrhiza glabra</i> (Yastimadhu, Klitaka (Substitute))	(Root)	1	Part
3	<i>Pluchea lanceolata</i> (Rasna)	(Leaf)	1	Part
4	<i>Desmodium gangeticum</i> (Salaparni)	(Root)	0.2	Part
5	<i>Uraria picta</i> (Prasniparni)	(Root)	0.2	Part
6	<i>Solanum xanthocarpum</i> (Kantakari, Laksamana (Substitute drugs) (Sveta))	(Root)	0.2	Part
7	<i>Solanum indicum</i> (Brahti)	(Root)	0.2	Part
8	<i>Tribulus terrestris</i> (Goksura)	(Root)	0.2	Part
9	<i>Pterocarpus santalinus</i> (Rakta candana)	(Heart Wood)	1	Part
10	<i>Gmelina arborea</i> (Gambhari)	(Fruit)	1	Part
11	<i>Sida cordifolia</i> (Bala)	(Root)	1	Part
12	<i>Solanum xanthocarpum</i> (Kantakari, Laksamana (Substitute drugs) (Sveta))	(Whole Plant)	1	Part

English

- 3. A composition as described above is formulated as (Decoction / Water Extract)(Kvatha)**
- 4. Therapeutic composition mentioned above is prepared by Kvatha Curna/Kvatha: Drugs are cleaned and dried.**
- 5. It is useful in the treatment of Small pox(Masurika)**

LIST OF DOCUMENTS WITH DATE OF PUBLICATION(PRIOR ART):

**Nagin Das Chagan lal
Saha**

**Bharat Bhaisjya Ratnakar, Gopi nath Bhisakratnen
Vol II B. Jain publishers (New Delhi) Ed. Reprint - August 1999.**

従来の知識資源のタイトル

Mañjiṣṭhādīkvāthah (Vṛhat) (08)

Japanese

その後知られている知識

500 years

TKRC Code : A01A-1/1225, A01A-1/1237, A01A-1/1351, A01A-1/1463, A01A-1/1482, A01A-1/1515, A01A-1/1547, A01A-1/1587, A01A-1/1590, A01A-1/1592, A01A-1/16, A01A-1/1664, A01A-1/1740, A01A-1/1824, A01A-1/1864, A01A-1/1883, A01A-1/1935, A01A-1/1938, A01A-1/1966, A01A-1/2000, A01A-1/2147, A01A-1/237, A01A-1/265, A01A-1/291, A01A-1/415, A01A-1/429, A01A-1/44, A01A-1/480, A01A-1/488, A01A-1/513, A01A-1/52, A01A-1/530, A01A-1/538, A01A-1/566, A01A-1/60, A01A-1/603, A01A-1/635, A01A-1/741, A01A-1/759, A01A-1/761, A01A-1/823, A01A-1/880, A01A-1/903, A01A-1/972, A01A-1/989, A01A-2/25, A01A-3/47, A01A-3/9, A01D-1/35, A01D-18/04, A01D-20/25, A01D-21/01, A01D-6/31, A01D-8/07, A01D-8/28, A01D-8/52, A01D-9/07, a01f-1/1

IPC コード : A61K35/78, A61K9/08, A61K9/14, A61P15/00, A61P17/00, A61P19/00, A61P19/02, A61P19/06, A61P21/00,

のプロセス/ 公式 :

1. Mañjiṣṭhādīkvāthah^a (Vṛhat) (08) 次のような有用な構成成分を含む治療的化合物製剤アカネ・カルジフォリア (マンジスタ), カヤツリグサ (ムスタカ), ホラレナ・アンチダイセンテリカ (クタジャ、インドラヤヴァ), タイノスポラ・コルジフォリア (グドウチ), モッコウ (クスタ), ジンギベル・オフィシネール (アルドラカ), クレロデンドラム・セツラタム (バランギ), ソレナム・ザントカルバム (カンタカリ, ラクサマナ (代用薬品) (スヴェタ)), アヤメガサ (ヴァチャ), アザジラクタ・インジカ (ニンバ), ウコン (ハリドラ), メギ・アリステタ (ダルハリドラ), カラスウリ・ダイオイカ (パトラ), コウレン (カトウキ), コンズランゴ・テネシシマ (ムルワ), エンベリア・ライプス (ヴィダンガ), プロテカルプス (ビジャカ (アサナ)), セイロンマツリ (チタラカ), アスパラガス・レスモサス (サタヴァリ, メダマハメダ (代用薬品)), リンドウ・クッルー (トラヤマツナ, トラヤンティ), キンマ・リンガム (ピツパリ), ホラレナ・アンチダイセンテリカ (クタジャ、インドラヤヴァ), アデトダ・ヴシカ (ヴァサ), タカサブロー・アルバ (ブリッガラジャ), ヒマラヤスギ・ヒマラヤスギ (デヴァダル), シサンペロス・パレイラ (パタ), アセンヤクノキ (カディラ), シタン (ラクタ・チャンダナ), オペルクリナ・タルパタム (トリワルタ), クラタエヴァ・ヌルヴェラ (ヴァルナ), センプリ・シライタ (キラタティクタ), ソレリア・コリリフォリア (バクキ), ナンバンサイカチ (アルガワダ), ストブラス・アスパル (サクホタカ), センダン・アゼダラク (マハニンバ, カイドリヤ?), ポンゲミア・ピンネタ (カラシヤ, ナクタマラ, ウドキリヤ), トリカプト・ヘテロフィツラム (アティヴィサ), サヤバナ・ヴェッティヴェロイデス (ハリベラ), スイカ・コロシンチス (インドラヴァルニ), ヘミデスマス・インジカス (サリヴァ (ウトパラ・サリヴァ)), フェマリア・パルヴィフロラ (パルパタ・ベータ), ファゴンタ・クレティカ (ダンヴィヤサ), テルミナリア・チェブラ (ハリタキ), テルミナリア・ベッリリカ (ビビタカ), エンブリカ・オフィシユナリス (アマルキー)

2. 治療的構成/製剤は以下の通り

1	アカネ・カルジフォリア (マンジスタ)	(根)	1	パート、部
2	カヤツリグサ (ムスタカ)	(茎・塊茎)	1	パート、部
3	ホラレナ・アンチダイセンテリカ (クタジャ、インドラヤヴァ)	(ステムバーク)	1	パート、部
4	タイノスポラ・コルジフォリア (グドウチ)	(ステム)	1	パート、部
5	モッコウ (クスタ)	(根)	1	パート、部
6	ジンギベル・オフィシネール (アルドラカ)	(根茎)	1	パート、部
		(根・塊茎)	1	パート、部

STATUS

Discipline	Current Status
Ayurvedic formulations	81,500
Unani formulations	1,09,500
Siddha formulations	12,200

TKDL ready to safeguard 2,03,200 medicinal formulations like Neem and Turmeric in Ayurveda ,Unani and Siddha which are present in 30 million A4 size pages, at International Level

TRADITIONAL MEDICAL MANUSCRIPTS (0.5 MILLION)

- **New Knowledge not known so far**
 - Enormous potential on creating new Traditional Medicines
 - Confidence and Trust for holder(s)
- **Protection (TKDL route)**
 - Conversion in 5 International Languages
 - Providing Access to IPOs
- **Dissemination & Knowledge Creation**
 - In Ten Indian Languages
 - Adding to the pool of existing knowledge

India's Strategy Non Disclosure Agreement with International Patent Offices

(CCEA has approved access to TKDL for International Patent Offices)

- **Users**

- Utilize for patent Search & Examination purposes only
- No third party Disclosures
- Give feedback on utilization of TKDL

- **Provider**

- 24 x 7 Access
- Training and support
- Search Assistance from TK experts

Current status on TKDL Access /Agreement

- **Access Agreement concluded with EPO in February 2009**
- **In principle agreement reached with USPTO, Agreement may get concluded soon.**
- **Effort being initiated with other patent offices.**

Views of EPO After Access to TKDL

- **An improved patent granting process at an early stage of patent examinations.**
- **A unique encyclopedia**
- **Shedding light on grey areas**
 - **TKDL is precise and TKRC ensures meticulous documentations**
 - **Thanks to TKDL, patent examiners can prove exactly when and where a medical treatment became public knowledge**

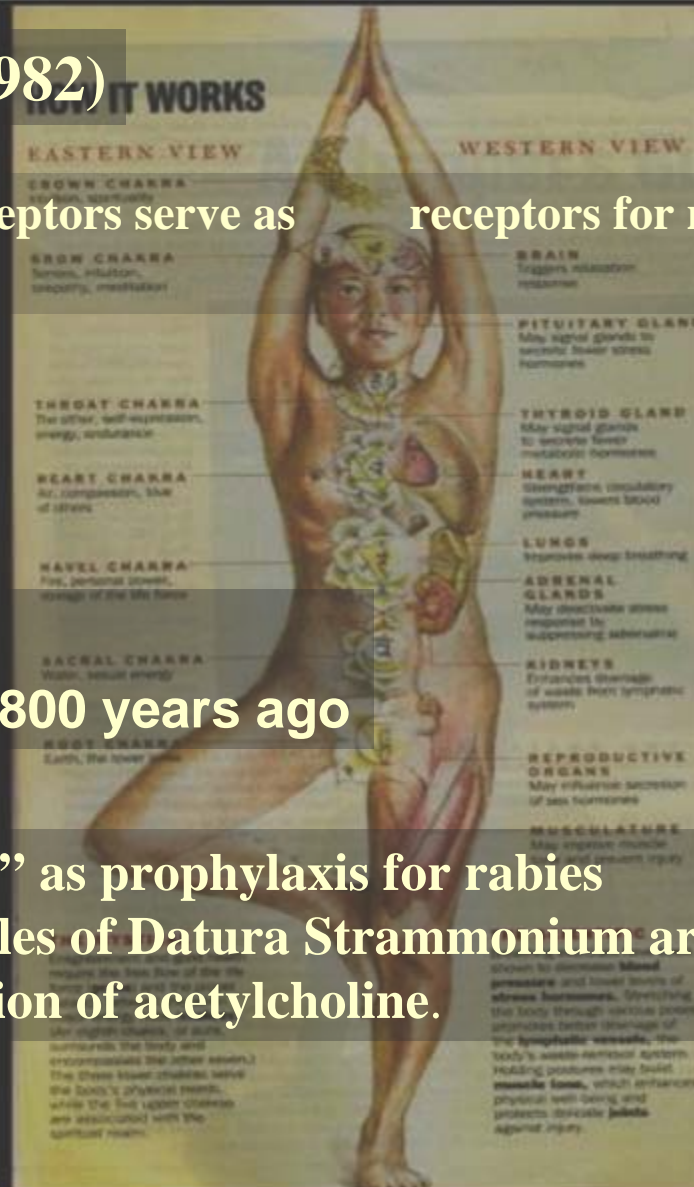
Harmonization of Traditional & Modern Medicines

Modern Science (1982)

Acetylcholine receptors serve as receptors for rabies virus (Lentz et al, Science)

Ancient Wisdom (Susruta Samhita) 1800 years ago

Describes “Datura” as prophylaxis for rabies
Active principles of Datura Stramonium are atropine blocking muscarine action of acetylcholine.



Traditional Medicine



**Modern
Medicine**

**Modern
Science**

Standard Drug Discovery Process

(molecule -> mice -> men)



Reverse Pharmacology Process



(men <-mice <- men)

Reverse Pharmacology

Alternative Path Making a Difference

Psoriasis (currently in Phase III)

	Drugs in USA	India
Cost of development	\$ Several Hundred millions	\$ 5 millions
Time for development	~10 yrs	3 yrs
Cost of treatment	\$20000	\$ 50

Pharma : Lowering R&D Product

GOLDEN TRIANGLE PROJECT (LIST OF FEW TARGET DISEASES)

- **Diabetes**
- **Memory disorders**
- **Joint disorders**
- **Sleep disorders**
- **Malaria/Filaria**
- **Cardiac disorders**
- **Bronchial allergy**
- **Vision disorders**

TKDL for Validation of Ayurveda, Unani, & Siddha against each other

All Indian Systems of Medicine have survived & grown in Indian Subcontinent

Used common Bio and Genetic Resources.

For Diseases of Subcontinent and its population.

جو اس میں تیوں ج نامیہ

اسہال بو اسیر بسیار مفید بلکہ اسہال خون و جگری راکہ ضعف در آن بسیار باشد و زرف الدم بہ عضو کیہ

Diseases and Common Indian Medicinal Plants

Malaria

System of Medicine	AYURVEDA	UNANI	SIDDHA	COMMON MEDICINAL PLANTS
NO. of Formulations in TKDL	1587	48	95	<i>Brahmi , Neerpirami, Sapthalai, Indravaruni,Pippali , Srmgika visa/</i>
Formulations in TKDL	Aindrirasayanam	Habb-e-bukhar	Sanda Marutha Kuzhamabu	<i>Vatsanabha ,Sarumam, Acacia arabica,Sambiran ipooundu</i>

Value Addition – Modern Science to TKDL

- ❑ Taxonomic Information, citation, synonyms, vernacular names, habitat, geographical information
- ❑ Morphological Information
- ❑ Cytological Information
- ❑ Germplasm Information

Value Addition – Modern Science to TKDL

- ❑ Pharmacological Information
- ❑ Phytochemistry
- ❑ Pharmacognostical Information
- ❑ Toxicology
- ❑ Utilization



Zoom 100%

COMPONENTS OF BIODIVERSITY DIGITAL LIBRARY

KINGDOM....Plantae
CLASS....Magnoliopsida (Dicotyledons)
FAMILY....Scrophulariaceae
GENUS....Bacopa Aubl.
SPECIES....Bacopa monnieri (Linn.) Penn.

Citation: in Proc. Acad. Nat. Sci. Philad.98:94, 1946;

Santapau in RBSI. 16(1) : 201, 1953.

Status: Abundant
known Since: 1756

TKDL TKRC:

Ploidy level:

Basic No.:

Chromosome No.:



SYNONYMS

LYSIMACHIA MONNIERI LINN. Cent. Pl. 2:9, 1756.

MONIERA CUNEIFOLIA MICHX. Fl. Bor-Amer. 2 : 22, 1803
(Monnieria);

VERNACULAR NAMES

English Water hyssop

Hindi Jalnim, Brahmi; Neem-jal; jal-lep.

Kannada Niru brahmi

Malayalam Nirbrahmi

Marathi Nirbrahmi

Bengali Brihmi-sak

Sanskrit Nira-Brahmi, Manduki

Tamil Nirbrahmi,

Telugu Sambrani chettu

MORPHOLOGY

Collaborative Research

- **Joint ownership of IP**
- **Participative Research & Development**
- **Technology transfer**
- **Institutional capacity Building**
- **Training**
- **Access to advanced Scientific Information**



Promoting Traditional Medicines & Balancing Patent Rights

- Enhance IPC for at least additional 2000 subgroups on traditional medicines to prevent misappropriations of Traditional Medicine
- Provide provisions at no cost to file third party observation at pre grant stage to establish prior art similar to article 115 of European Patent Convention
- Patent offices to employ examiners skilled in traditional medicine such as, Ayurveda, Unani etc.

Promoting Traditional Medicines & Balancing Patent Rights

- Public Health Regulators to consider grant of approval for efficacy, since safety requirements are already well established
- Patent offices review past wrong patents and get them invalidated once evidence on prior art gets established
- Open TM databases to be included in PCT minimum documentation.

Promoting Traditional Medicines & Balancing Patent Rights

- Mere discovery of new form/ new use of known substance not resulting in efficacy enhancement
- Submission of developing countries at TRIPS Council concerning source of origin, evidence of Benefit Sharing and Prior Informed Consent on patent applications based on Traditional Knowledge and associated Genetic Resources

ΛΙΟΝ
ΚΑΤΑ
ΜΑΡΚΟΝ

THANKS

ρχη των ευαγγελιων εν τω

ταυτην

γεγραμμενον

ισκατασκειν ασφθηω οδω

σοφιας οργεσθη τη ερημωσει

μασαστε τηω οδω τω

ωιθητε τας τριμονσων του

515



2
1