

**The INDIAN “TRADITIONAL KNOWLEDGE” (TKDL) DATABASE:  
A BAR TO PATENTING THE KNOWN PLANTS OF INDIA?\***

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**I. OVERVIEW**

The English language Traditional Knowledge Digital Library (TKDL) provides Examiner access to original Sanskrit and other documents which disclose the varied plants of India’s “traditional knowledge”: Assuming a plant described in the TKDL has only been used in India, to what extent does disclosure of such a plant in the TKDL create a bar to a United States patent?

This topic has generated some controversy in view of a recent inter-governmental agreement between the United States and India. *See* § II, *U.S.-India Agreement to Share the TKDL Database*. The TKDL represents a positive step to explain literally thousands of traditional plant remedies to the modern world. *See* § III, *Achievement of the TKDL Database*. Questions are

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\* This paper represents the views of the writer and does not necessarily reflect the views of any colleague, organization or client thereof.

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raised as to whether and under what conditions a scientist who rediscovers a traditional Indian plant may still be able to obtain valid American patents, *despite* publication in the TKDL Database. *See § IV, Does the TKDL Database Defeat Patentability?*

A sophisticated scientist may well modify plant characteristics through breeding or genetic engineering techniques or simply identify characteristics that have not been explicitly set forth in the TKDL Database. Questions then must be asked concerning novelty and nonobviousness for inventions to plants which include specific characteristics which are either novel or which have not previously been identified. *See § V, Novelty and Nonobviousness Considerations*

## **II. U.S.-INDIA AGREEMENT TO SHARE THE TKDL DATABASE**

As part of a November 2009 State visit of Indian Prime Minister Dr. Manmohan Singh to the United States, an Indian government representative and U.S. Deputy Under Secretary of Commerce for Intellectual Property Sharon R. Barner signed an agreement that will better disseminate in the United States information about Indian "traditional knowledge", a rich source of information that holds the promise to unlocking secrets to create new therapies and better foodstuffs. The agreement gives the United States access to India's Traditional Knowledge Digital Library which will also provide a prior art source to reject claims to *known* plants.

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The PTO has announced plans to have Examiners *deny* claims to known plants in the Traditional Knowledge Digital Library database even though they have only been used or sold in India.

### **III. ACHIEVEMENT OF THE TKDL DATABASE.**

Professors Munzer and Raustiala explain that when completed, "[t]he TKDL will contain around thirty million pages of Indian ancient and traditional knowledge translated into other languages and arranged according to the International Patent Classification." Stephen R. Munzer & Kal Raustiala, *The Uneasy Case for Intellectual Property Rights in Traditional Knowledge*, 27 *Cardozo Arts & Ent. L.J.* 37, 52 (2009). Professor Erstling explains that "the TKDL is a collaborative project of a number of Indian Government institutes and ministries, the objective of which is to document the body of knowledge that is available in the public domain on the traditional Indian systems of medicine and to protect that knowledge from misuse by third parties attempting to obtain patents on non-novel and obvious innovations." Jay Erstling, *Using Patents To Protect Traditional Knowledge*, 15 *Tex. Wesleyan L. Rev.* 295, 320 (2009) (footnotes omitted). The TKDL puts into modern wording "ancient texts in Sanskrit, Urdu, Persian, or other generally inaccessible languages and passed down by word of mouth." *Id.*

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### **IV. DOES THE TKDL DATABASE DEFEAT PATENTABILITY?**

If a plant is disclosed in the TKDL English language database, does this defeat patentability as a "printed publication" to bar a claim to that plant?

Several interesting issues are raised which have yet to be fully addressed by the PTO, although some guidance has been provided in the *Manual of Patent Examining Procedure* (excerpted at page 14 as an appendix).

#### **A. Is the English TKDL Database *Retroactively* "Prior Art"?**

While the English language TKDL database may be prior art against *future* inventions, it is questionable whether it is prior art against patent applications *already on file*. But, the point is rendered moot to the extent that the underlying original language Sanskrit or Urdu or other document is a "printed publication" within the meaning of 35 USC § 102(b). Thus, citation of an English TKDL database reference will, insofar as it is used in relation to an *existing* patent application not be prior art, *per se*, but rather a search tool for anyone seeking to deny a patent or invalidate an existing patent to find the original Sanskrit or Urdu document.

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### **B. Is the English TKDL Database Publicly Accessible?**

The fact that the TKDL database is available to Examiners in the EPO and the U.S. PTO may or may not suffice for public accessibility necessary to qualify the TKDL Database as prior art. But, it is understood that the U.S. PTO in any event plans to make the Database open to public use.

But, the TKDL Database will in any event principally serve as a *search tool* to help the American and European patent communities have better access to the original Sanskrit and Urdu documents, rendering moot the question as to whether the English TKDL Database is or is not a “printed publication”.

As pointed out by Professor Erstling, the TKDL is designed not as a source of prior art but to point patent examiners toward the prior art. Indeed, Professor Erstling opines that “the TKDL does not itself constitute the prior art; the TKDL serves as the reference tool that points examiners to the texts that constitute it.” Erstling at 320 (footnote deleted).

### **C. Is a Sanskrit or Urdu Document Available Only in India “Prior Art”?**

A document in *Sanskrit*, *Urdu* or any of the other major Indian native languages is available to a huge segment of the public (albeit mainly in India) and constitutes a “printed publication” within the meaning of 35 USC § 102(b). This is true if the document is *accessible* even if it has never been proven to have been actually accessed:

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[A] printed publication may be an effective bar to the granting of a patent if it is in this or a foreign country. 35 U.S.C. 102(a, b). For knowledge or use of the invention to be a statutory bar, however, it must be in this country. 35 U.S.C. 102(a). ...[W]hat Congress was concerned with, both in [the new patent laws of] 1836 and 1952, was the probability that the subject matter would be made known to the American public. Knowledge and use in the United States would probably (or so Congress must have reasoned) come to the attention of the American people whereas the same probability would not be present with respect to such knowledge and use abroad. By the same token, in the case of 'printed' publications, Congress no doubt reasoned that one would not go to the trouble of printing a given description of a thing unless it was desired to print a number of copies of it.

.....

But though the law has in mind the probability of public knowledge of the contents of the publication, the law does not go further and require that the probability must have become an actuality. In other words, once it has been established that the item has been both printed and published, it is not necessary to further show that any given number of people actually saw it or that any specific number of copies have been circulated. The law sets up a conclusive presumption to the effect that the public has knowledge of the publication when a single printed copy is proved to have been so published.

*Bruckelmyer v. Ground Heaters, Inc.*, 453 F.3d 1352, 1353-54 (Fed. Cir. 2006)(Newman, J., joined by Linn, J., dissenting from denial of the petition for rehearing en banc)(quoting *In re Tenney*, 254 F.2d 619, 626-27 (CCPA 1958)(Johnson, C.J.)).

Even if there were only limited circulation or availability of a printed publication because of a remote location to access the printed publication, this would not defeat the status of the printed publication as prior art under 35 USC § 102(b). Thus, in a case that is now more than fifty years old when a microfilm reference was held not to be a "printed publication", at the same time even then a

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single copy of a Southern Rhodesian patent file accessible only in that remote former colonial Territory was considered a "printed publication":

[T]he present law [concerning a statutory bar under 35 USC § 102(b)] is anomalous, as evidenced by our conclusion that [a] microfilm [document] is not 'printed' [and hence not 'prior art']. A foreign patent file, laid open for public inspection, is not a printed publication, because typewritten, while a printed publication, available to the public only in a Southern Rhodesian library, would be. The [microfilm document] is obviously more likely to reach the eyes of the American public than the [Southern Rhodesian patent].

*In re Tenney*, 254 F.2d 619, 627 (CCPA 1958)(Johnson, C.J.). (In the meantime, the holding in *Tenney* has been overruled to the extent that any microfilm – or other – document that is indexed and available to the public is a "printed publication" within the meaning of 35 USC § 102(b). *See, e.g., In re Wyer*, 655 F.2d 221 (CCPA 1981)(Rich, J.)

Today, the debate over whether a disclosure is a "printed publication" has moved into the electronic ether and focuses on whether posting of information on the Internet is prior art. (In one recent case, a panel majority found such posting to be a "printed publication" only with certain limitations, *SRI Intern., Inc. v. Internet Sec. Systems, Inc.*, 511 F.3d 1186 (Fed. Cir. 2008)(Rader, J.), while a third member found the posting, without more, to create a patent-defeating printed publication, *SRI*, 511 F.3d at 1198 (Moore, J., dissenting).)

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### D. The Critical Question: Is there an *Enabling* Disclosure?

The disclosure of a plant in the TKDL database does not, *without more*, provide a patent-defeating effect to bar patenting of the same plant because the TKDL database does not provide an *enabling* disclosure of the plant. Thus, merely reading the TKDL database entry does not provide a teaching of how one would reproduce or otherwise obtain the plant. The case, here, is factually similar to *In re LeGrice*, 301 F.2d 929 (CCPA 1962), where a printed publication of a rose sold only abroad was held not anticipatory as to a claim to the rose, *per se*, because the publication was not itself enabling. (*LeGrice* is discussed by the PTO in the *Manual* excerpt reproduced at page 14.)

It is thus critical to know whether, given the TKDL database entry – in English or Sanskrit – one skilled in the art is directed to a source for the plant. Although *LeGrice* remains good law in the sense of the requirement for an enabling disclosure to support a "printed publication" as a patent-defeating document, modern case law has circumvented the *LeGrice* obstacle by viewing a printed publication that refers to a source for the plant as an incorporation-by-reference of such an enabling disclosure.

Until *In re Elsner*, 381 F.3d 1125, 1129 (Fed. Cir. 2004)(Lourie, J), the point concerning whether a TKDL database entry would defeat patentability would have been whether an *Indian* source for the plant is sufficient to supply

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enablement. In other words, because a prior use of an invention must be *domestic* under 35 USC § 102(a), what impact would this have on the TKDL database entry? (*Elsner* is discussed by the PTO in the *Manual* excerpt reproduced at page 14.)

Now, per *Elsner*, there is no longer any real controversy over this point, as exemplified by the case of *Ex parte Boeder*, 2009 WL 3089031 (PTO Bd.Pat.App. & Interf. 2009). In *Boeder*, the PTO denied a claim to a plant, the chrysanthemum “Cetwotone Pink”, which was regularly sold abroad but never in the United States, but which *was* identified in a printed publication.

Distinguishing *Le Grice* in the *Boeder* case, the Board held that the *publication* that fingerprinted the identity of the claimed chrysanthemum “Cetwotone Pink” is a statutory bar under 35 USC § 102(b) based upon the foreign sales of this plant:

When a [printed] publication [under 35 USC § 102(b)] identifies the [claimed] plant ...and a foreign sale occurs that puts one of ordinary skill in the art in possession of the plant itself, which, based on the level of ordinary skill in the art, permits asexual reproduction without undue experimentation, that combination of facts and events so directly conveys the essential knowledge of the invention that the sale combines with the publication to erect a statutory bar.

*Ex parte Boeder* (quoting *Elsner*, 381 F.3d 1125 at 1129).

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### E. May a Foreign Language Publication be Used to Show Enablement?

While a foreign language publication *is* "prior art" for purposes of 35 USC § 102(b), the question of whether a foreign language book or article may provide *enablement* to defeat a claim was cast in doubt in a decision nearly thirty years ago. The relevant statement concerning a foreign language text is *dictum* because the statement was unnecessary to the decision which in any event was against the patent applicant:

Well known text books in English are obvious research materials. Similarly, public records concerning U.S. patents are likely to be checked, and information therein is reasonably accessible in view of the published abstracts and our classification system. Thus, U.S. patents are considered pertinent evidence of what is likely to be known by persons of ordinary skill in the art. *We do not exclude the possibility that foreign patents and foreign language printed publications may also be relevant to the inquiry of what is likely to be known, but we do not ipso facto give all patents and printed publications the same evidentiary weight for purposes of showing enablement under § 112, even though all such references are treated the same for prior art purposes under § 102.*"

*In re Howarth*, 654 F.2d 103, 106-07 (CCPA 1981)(Nies, J.)(emphasis added; footnote omitted).

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More recently in *Atmel*, the court quoted from *Howarth* with approval: “A reference is reasonably accessible to the public, for example, if its incorporation would not be necessary because it is ‘common or well known,’ such as ‘[w]ell known text books in English’ and ‘U.S. patents[.]’” *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1386 (Fed. Cir. 1999)(Lourie, J.) (quoting *Howarth*, 654 F.2d at 106)

## **V. NOVELTY AND NONOBVIOUSNESS CONSIDERATIONS**

It may often be the case that a scientist can identify characteristics for a plant that are not explained in the TKDL Database. What happens if the claim to the plant includes such specific points of identification which cannot be found in the TKDL database?

*In re POD-NERS, L.L.C.*, \_\_ Fed.Appx.\_\_, 2009 WL 2029976 (Fed. Cir. 2009)(per curiam) illustrates the problems that a patent applicant will need to surmount to overcome a prior art disclosure of the plant.

In *POD-NERS*, patentee Larry Proctor took a trip to Mexico where he purchased beans that he then modified by harvesting and planting over a three year period. One of the patented beans has “a yellow coat described as within a narrow range of shades of yellow on a particular color chart. The other covered a bean ‘designated Enola as deposited in’ the American Type Culture Collection under a specified ‘accession number.’” The specification identifies “the Enola bean as a ‘cultivar’ of common field beans plants and seeds.”

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The Board in the opinion below denied patentability on the basis that the Enola bean was in essence the same as "a well-known yellow bean called 'Azufrado Peruano 87,' which was disclosed in an article by Salinas. The Board found that the Azufrado Peruano 87 plant and seed reasonably appeared to be substantially the same as the Enola plant and seed. The common characteristics of both included that they are yellow-seeded cultivars. The Board also relied on a published article by Pallotinni and others stating and comparing the genetic fingerprints of Enola and Azufrado Peruano 87 and concluding that 'the DNA fingerprint of ENOLA is identical to a fingerprint found in Mexican yellow-seeded beans of the Peruano group.'"

The obviousness rejection under 35 USC § 103(a) was affirmed by the Court:

One of ordinary skill in the art seeking to reproduce (and hopefully improve) the yellow beans that Proctor brought back from Mexico would have done what he did: plant the beans, harvest the resulting plants for their seeds, planting the latter seeds, and repeat the process two more times.

There is no indication that in taking these steps Proctor sought to provide beans of the particular narrow range of yellow that the claims specified. To the contrary, it appears that all Proctor was attempting to do was to reproduce the yellow beans he had acquired in Mexico, and hopefully to improve them.

To do so he followed normal and well-established agricultural methods and techniques for doing that. *See KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 418 ('a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.') He does not contend that he devised or applied new or unexpected techniques in reproducing the beans.

... Proctor does not argue that seed coats falling within a particular range of yellow colors have any meaningful impact on the properties of the beans. Nor did

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he provide objective evidence of secondary considerations that might show nonobviousness—that the particular shades of yellow resulted in substantial sales of the Enola beans, that there was a long need for beans of that color that others were unable to supply, or that others copied the Enola bean. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

...Pallotinni, while not itself prior art, because [it was after the filing date], describes the Enola bean as being quite similar or even identical to the Azufrado Peruano plants earlier described by Salinas et al., which is prior art. ('Our results show that the DNA fingerprint of Enola is identical to a fingerprint found in Mexican yellow-seeded beans of the Peruano group.')

Thus, while the Pallotinni reference by itself could not render the present claims obvious, Salinas, as understood by Pallotinni, did render them obvious, if not anticipated. In fact, as noted, Proctor bought the seeds in question in Mexico and brought them home to be planted in the United States. While being on sale, in public use, or known or used outside the United States, which the Azufrado beans surely were, are not statutory bars, *see* 35 U.S.C. § 102, publications such as Salinas, describing the beans and being interpreted by Pallotini, are." ...

In *KSR*, 550 U.S. at 421, the Supreme Court pointed out that 'rigid preventative rules that deny fact finders recourse to common sense, however, are neither necessary under our case law nor consistent with it.' To reject the Board's obviousness ruling here, would be to deny the Board that very 'recourse to common sense' that the Supreme Court there warned against.

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### *PTO Manual of Patent Examining Procedure:*

#### **Those of Ordinary Skill Must be Able to Grow and Cultivate the Plant**\*

[The prior art] reference, combined with knowledge in the prior art, must enable one of ordinary skill in the art to reproduce the plant [to defeat a claim to a plant]. *In re LeGrice*, 301 F.2d 929 (CCPA 1962) (National Rose Society Annual of England and various other catalogues showed color pictures of the claimed roses and disclosed that applicant had raised the roses. ... The court held that the publications did not place the rose in the public domain. Information on the grafting process required to reproduce the rose was not included in the publications and such information was necessary for those of ordinary skill in the art (plant breeders) to reproduce the rose.). Compare *Ex parte Thomson*, 24 USPQ2d 1618 (Bd. Pat. App. & Inter. 1992) (Seeds were commercially available .... One of ordinary skill in the art could grow the claimed cotton cultivar from the commercially available seeds. Thus, the publications describing the cotton cultivar had "enabled disclosures." The Board distinguished *In re LeGrice* by finding that the catalogue picture of the rose of *In re LeGrice* was the only evidence in that case. There was no evidence of commercial availability in enabling form since the asexually reproduced rose could not be reproduced from seed. Therefore, the public would not have possession of the rose by its picture alone, but the public would have possession of the cotton cultivar based on the publications and the availability of the seeds.).

In *In re Elsner*, 381 F.3d 1125, 1126 (Fed. Cir. 2004), prior to the critical date of a plant patent application, the plant had been sold in Germany and a foreign Plant Breeder's Rights (PBR) application for the same plant had been published in the Community Plant Variety Office Official Gazette. The court held that when (i) a publication identifies claimed the plant, (ii) a foreign sale occurs that puts one of ordinary skill in the art in possession of the plant itself, and (iii) such possession permits asexual reproduction of the plant without undue experimentation to one of ordinary skill in the art, then that combination of facts and events directly conveys the essential knowledge of the invention and constitutes a 35 U.S.C. 102(b) statutory bar. 381 F.3d at 1129. Although the court agreed with the Board that foreign sales may enable an otherwise non-enabling printed publication, the case was remanded for additional fact-finding in order to determine if the foreign sales of the plant were known to be accessible to the skilled artisan and if the skilled artisan could have reproduced the plant asexually after obtaining it without undue experimentation. 381 F.3d at 1131.

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\* MPEP § 2121.03. Plant Genetics – What Constitutes Enabling Prior Art (8th ed. [Rev. 7] July 2008).