

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Request for Reexamination of

**U.S. Patent No. Plant 5,751
(Patentee: Loren S. Miller)**

Issued: June 17, 1986

Primary Examiner: James R. Feyrer

Filed: Nov. 7, 1984

For: *BANISTERIOPSIS CAAPI* (cv) "DA VINE"

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**DETAILED STATEMENT IN SUPPORT OF REQUEST FOR
REEXAMINATION OF U.S. PLANT PATENT NO. 5,751**

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

This request is for reexamination, pursuant to 37 C.F.R. § 1.510, of Claim 1 of U.S. Plant Patent No. 5,751 (the "Da Vine Patent"), which issued June 17, 1986 in the name of Loren S. Miller ("Miller"). The request is made in view of the following prior art:

1. Plants of Cultivation: *Banisteriopsis caapi*, Accessioned Specimen Sheet, The University of Michigan Herbarium (mounted Jan. 5, 1981) [Exhibit No. 1].
2. Plants of Cultivation: *Banisteriopsis caapi*, Field Museum of Natural History Herbarium Accession Sheet No. 1823910 (mounted April 24, 1978) [Exhibit No. 2].
3. Plants of Florida: *Banisteriopsis caapi*, Field Museum of Natural History Herbarium Accession Sheet No. 1910734 (mounted March 28, 1983) [Exhibit No. 3].

4. Plants of Florida: *Banisteriopsis caapi*, Field Museum of Natural History Herbarium Accession Sheet No. 1910747 (mounted March 28, 1983) [Exhibit No. 4].
5. Dobkin de Rios, Marlene, *A Note on the Use of Ayahuasca Among Urban Mestizo Populations in the Peruvian Amazon*, 72 *Am. Anthropologist* 1419-21 (1970) [Exhibit No. 5].
6. Dobkin de Rios, Marlene, *Banisteriopsis in Witchcraft and Healing Activities in Iquitos, Peru*, 24 *Econ. Botany* 296-99 (1970) [Exhibit No. 6].
7. Dobkin de Rios, Marlene, *Ayahuasca—The Healing Vine*, 27 *Int'l J. Soc. Psychiatry* 256-67 (1971) [Exhibit No. 7].
8. Dobkin de Rios, Marlene, *The Wilderness of Mind: Sacred Plants in Cross-Cultural Perspective* 69-73 (Sage Research Paper No. 90-039, 1976) [Exhibit No. 8].
9. Dobkin de Rios, Marlene, *Visionary Vine: Psychedelic Healing in the Peruvian Amazon* 38-47, 67-76, 88, 99-116, 129-40 (Chandler Pub. for Health Sciences, 1972) [Exhibit No. 9].
10. Flores, Franklin Ayala & Walter H. Lewis, *Drinking the South American Hallucinogenic Ayahuasca*, 32 *Econ. Botany* 154 (1978) [Exhibit No. 10].
11. Hill, Albert F., *Economic Botany: A Textbook of Useful Plants and Plant Products* 283-84 (2d ed. 1952) [Exhibit No. 11].
12. Rivier, Laurent & Jan-Erik Lindgren, "Ayahuasca," *the South American Hallucinogenic Drink: An Ethnobotanical and Chemical Investigation*, 26 *Econ. Botany* 101-03, 117 (1972) [Exhibit No. 12].
13. Schultes, Richard Evans & Albert Hofmann, *The Botany and Chemistry of Hallucinogens* 163-81 (American Lecture Series No. 1025, 1980) [Exhibit No. 13].
14. Briggs, D. & S.M. Walters, *Plant Variation and Evolution* 93-94 (1969) [Exhibit No. 14].
15. Stace, Clive A., *Plant Taxonomy and Biosystematics* 186-90 (1980) [Exhibit No. 15].
16. Stebbins, G. Ledyard, Jr., *Variation and Evolution in Plants* 72-6 (1950) [Exhibit No. 16].

I. INTRODUCTION

This request for reexamination is being filed by the Center for International Environmental Law (CIEL), on behalf of the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) and the Coalition for Amazonian Peoples

and Their Environment (Amazon Coalition). CIEL is a non-profit organization that promotes sustainable and equitable development and environmental protection through the development and implementation of international law. COICA is the coordinating body for more than 400 indigenous cultures that are members of nine national organizations of the countries in the Amazon region. The Amazon Coalition is comprised of eighty non-governmental organizations dedicated to strengthening and broadening the alliance between indigenous peoples of the Amazon and groups who share their concerns for the future of the Amazon and its peoples.

The Requesters respectfully seek a determination by the United States Patent and Trademark Office (“PTO”) on the issue of whether the above-referenced prior art raises a substantial new question of patentability regarding Claim 1, the sole claim of the patent. This claim is for a new and distinct variety (cultivar) of the species *Banisteriopsis caapi*, dubbed “Da Vine” by Miller, the patent applicant. A cut-up copy of the patent is attached hereto as Exhibit No. 21.

Part II of this Request summarizes the patent as claimed. Part III briefly describes the new prior art. Part IV identifies substantial new questions of patentability.

Part V explains the pertinence and manner of applying the prior art. As explained in Section A, a review of the prior art reveals that the “Da Vine” cultivar is neither distinct nor new, because the medicinal and morphological characteristics on which the claim is based are well within the normal range of variation for individual plants of the species, and both the species and the characteristics described in the patent are well known, not only in the scientific literature, but also in the systems of traditional knowledge of indigenous groups throughout the Amazon. As explained in Section B, the “Da Vine” cultivar, like other forms of the species *B. caapi*, cannot be patented under the explicit terms of the Plant Patent Act because it is “found in an uncultivated state.” See 35 U.S.C. § 161.

Finally, as explained in Section C, even if the “Da Vine” cultivar did constitute a distinct and new variety (which it does not), prior art reveals that issuance of the Patent does not meet the public policy and morality aspects of the Patent Act, which preclude awarding a patent on a plant such as *Banisteriopsis caapi* that is sacred to indigenous peoples throughout the Amazon region and has been used and revered in their cultures for

many generations. Awarding patent rights over a plant that is widely found in an uncultivated state in other countries, and as such is a recognized part of the natural resources within their sovereign control, is also contrary to public policy. Additionally, the PTO should not provide patent protection to a plant based on supposed medicinal characteristics that are well known in the systems of traditional knowledge of indigenous peoples of the areas where the plant is found. As illustrated by recent policy statements from the PTO, as well as analogous decisions on trademark registration, the PTO may and should decline to award intellectual property rights where their imposition would violate established moral, religious and cultural values.

II. THE PATENT AS CLAIMED

The first and only claim of the Patent Application is for a new and distinct variety (cultivar) of the species *Banisteriopsis caapi*. Da Vine Patent, col. 4 [Exhibit No. 21]. *B. caapi* is a species of liana vine of the family *Malpighiaceae*, which grows wild throughout the Amazon region of South America. See Richard Evans Schultes & Albert Hofmann, *The Botany and Chemistry of Hallucinogens* 163, 181 (American Lecture Series No. 1025, 1980) [Exhibit No. 13]. *B. caapi* is also widely cultivated by indigenous peoples of the region for use in their religious ceremonies. See Albert F. Hill, *Economic Botany* 283 (2d ed. 1952) [Exhibit No. 11]; Bronwen Gates, *Banisteriopsis, Diplopterys (Malpighiaceae)* 113 (Flora Neotropica Monograph No. 30, 1982) [Exhibit No. 20] [hereinafter the Gates Monograph].

In the Patent Application, Miller claims to have invented a “new and unique” variety of *B. caapi*, distinguished from typical forms of the plant by:

- leaves of different sizes, shapes, and texture;
- different size pedicels;
- greater pubescence;
- different flower color and size; and
- absence of samaras, or nuts (i.e., the plant is sterile).

The patent states that the new variety is “particularly characterized” by the “rose color of its flower petals which fade with age to near white,” and by its “medicinal properties.” Da Vine Patent, Exhibit No. 21, abstract. In summarizing the “invention,”

the patent claims that the new variety “is an attractive house plant which seasonally blooms,” and that it is “being investigated for its medicinal value.” *Id.* col. 1. Although the patent mentions therapeutic applications of the variety, it does not claim that those applications are in any way different from those of other forms of *B. caapi*.

The specifications upon which the patent claims that the new variety is distinctive from typical forms of *B. caapi* were derived solely from a comparison between a plant grown by Miller at Harold Lyon Arboretum, Oahu, Hawaii, and the description of *B. caapi* contained in the Gates Monograph. *Compare* Gates Monograph, *supra* Exhibit No. 20, at 112 *with* Da Vine Patent, Exhibit No. 21, col. 4. The patent does not mention any comparisons having been made with mounted specimens from the public collections of the major herbaria located in the United States that specialize in the Malpighiaceae family or in plants of the region where the sample of *B. caapi* was collected.

III. THE NEW PRIOR ART

A. Prior Art Under 35 U.S.C. § 102(a)

The following herbarium accession sheets demonstrate that “Da Vine” was known or used by others in this country long before Miller’s “invention” of the purported new cultivar. They show specimens of *B. caapi* with flower color similar or identical to that of “Da Vine,” taken from specimens that were planted in the United States in the 1960s and 1970s.

1. Plants of Cultivation: *Banisteriopsis caapi*, Accessioned Specimen Sheet, The University of Michigan Herbarium (mounted Jan. 5, 1981) [Exhibit No. 1]. This sheet shows a specimen of *B. caapi* collected by Dr. Timothy Plowman. It contains his notes describing the specimen as having flowers that are “deep pink turning white with age.” The specimen was taken from an individual planted in Miami, Florida in 1974.

2. Plants of Cultivation: *Banisteriopsis caapi*, Field Museum of Natural History Herbarium Accession Sheet No. 1823910 (mounted April 24, 1978) [Exhibit No. 2]. This sheet shows a specimen of *B. caapi* collected by Dr. Timothy Plowman. It contains his notes describing the specimen as having flowers that are “deep pink turning white with age.” The specimen was taken from an individual that was planted in Miami, Florida in 1974.

3. Plants of Florida: *Banisteriopsis caapi*, Field Museum of Natural History Herbarium Accession Sheet No. 1910734 (mounted March 28, 1983) [Exhibit No. 3]. This sheet shows a specimen of *B. caapi* collected by Dr. Timothy Plowman (Plowman coll. no. 12972). It contains his notes describing the specimen as having flower buds “deep rose pink. Petals rose pink, the limb fading to creamy white with age, the claw remaining pale pink.” The specimen was taken from an individual that was planted in South Miami, Florida, which had been grown from a cutting collected in Ecuador in August 1979.¹

4. Plants of Florida: *Banisteriopsis caapi*, Field Museum of Natural History Herbarium Accession Sheet No. 1910747 (mounted March 28, 1983) [Exhibit No. 4]. This sheet shows a specimen of *B. caapi* collected by Dr. Timothy Plowman (Plowman coll. no. 12973). It contains his notes describing the specimen as having flower petals that are “rose pink, fading completely white with age.” The specimen was taken from an individual planted in South Miami, Florida that had been grown from a cutting collected in Peru in August 1967.

B. Prior Art Under 35 U.S.C. § 102(b)

The following prior art demonstrate that the purported “Da Vine” cultivar, which is indistinct from other forms of *B. caapi*, was described by its form and usage in printed

¹ The Da Vine Patent Application states that it is a “continuation application of application Ser. No. 266,114, filed on May 21, 1981 now abandoned.” The effective date for purposes of determining prior art under 35 U.S.C. 102 typically is the earlier filing date, rather than the filing date of the actual application (in this case, November 7, 1984). However, the Da Vine Patent Application relies exclusively on a comparison with the Gates Monograph to establish its claims of novelty and distinctness. *Compare* Da Vine Patent, Exhibit No. 21, col. 4 *with* Gates Monograph, *supra* Exhibit No. 20, at 112-13; *see also* Anderson Declaration, Exhibit No. 17, ¶ 2 (stating appropriateness of Miller comparing his specimen with Gates’ description, because the Gates Monograph was the only modern monograph available at the time). Because the actual application relies solely on a publication dated *after* the filing of the abandoned application, the logical date to use as a cut-off for consideration of prior art under this Request for Reexamination is the date of the actual application (November 7, 1984), rather than that of the abandoned application. Consequently, Exhibits 3 and 4—added to the Field Museum’s collections after the abandoned filing date, but over a year before the date of the actual Da Vine Application—should be considered prior art for the purposes of this Request.

Even if Exhibits 3 and 4 are not considered prior art for the purposes of this Request, they nonetheless provide evidence that the putative “Da Vine” variety was in use in this country before the time of its purported invention. Moreover, Exhibits 1 and 2 were accessioned before both the earlier abandoned application date and the later Da Vine application date. They thus provide sufficient prior art to justify reexamination even if Exhibits 3 and 4 are considered to be evidence of prior use, and not prior art.

publications in this country more than one year prior to the date of the Da Vine Patent Application.

1. Plants of Cultivation: *Banisteriopsis caapi*, Accessioned Sheet, The University of Michigan Herbarium (mounted Jan. 5, 1981) [Exhibit No. 1]. As described above.

2. Plants of Cultivation: *Banisteriopsis caapi*, Field Museum of Natural History Herbarium Accession Sheet No. 1823910 (mounted April 24, 1978) [Exhibit No. 2]. As described above.

3. Plants of Florida: *Banisteriopsis caapi*, Field Museum of Natural History Herbarium Accession Sheet No. 1910734 (mounted March 28, 1983) [Exhibit No. 3]. As described above.

4. Plants of Florida: *Banisteriopsis caapi*, Field Museum of Natural History Herbarium Accession Sheet No. 1910747 (mounted March 28, 1983) [Exhibit No. 4]. As described above.

5. Dobkin de Rios, Marlene, *A Note on the Use of Ayahuasca Among Urban Mestizo Populations in the Peruvian Amazon*, 72 *Am. Anthropologist* 1419-21 (1970) [Exhibit No. 5]. This article is based on a year-long study of psychotherapeutic use of ayahuasca by mestizo folk healers in the Peruvian Amazon. (“Ayahuasca” is both the common name for *B. caapi* and the name of a potion derived from the plant’s bark.) The article describes how *B. caapi* is used by shamans there as a diagnostic tool for treating a wide array of organic malfunctions that are often of emotional or psychological origin.

6. Dobkin de Rios, Marlene, *Banisteriopsis in Witchcraft and Healing Activities in Iquitos, Peru*, 24 *Econ. Botany* 296-99 (1970) [Exhibit No. 6]. This article describes how ayahuasca is used by specialized healers in the Amazon to identify and cure psychosomatic illnesses believed to be brought on by witchcraft.

7. Dobkin de Rios, Marlene, *Ayahuasca—The Healing Vine*, 27 *Int’l J. Soc. Psychiatry* 256-67 (1971) [Exhibit No. 7]. This article discusses how *B. caapi* has been known and cultivated by traditional Amazon Indian groups for centuries, describes ayahuasca healing sessions, and identifies the various “magical illnesses” treated in the healing sessions.

8. Dobkin de Rios, Marlene, *The Wilderness of Mind: Sacred Plants in Cross-Cultural Perspective* 69-73 (Sage Research Paper No. 90-039, 1976) [Exhibit No. 8].

This book includes a table listing the traditional ways in which *B. caapi* is used by specific traditional Amazonian societies. Each listing includes bibliographic references.

9. Dobkin de Rios, Marlene, *Visionary Vine: Psychedelic Healing in the Peruvian Amazon* 38-47, 67-76, 88, 99-116, 129-40 (Chandler Pub. for Health Sciences, 1972) [Exhibit No. 9]. This book provides a table listing the ways in which numerous indigenous Amazonian societies use *B. caapi* for religious purposes, divination (prophesying, spiritual communication, etc.), witchcraft, the treatment of disease, and social interaction. It contains in-depth accounts of ayahuasca healing sessions and the use of ayahuasca to treat psychosomatic illness, provides biographies of several ayahuasca healers and their patients, and analyzes the mechanisms of ayahuasca healing.

10. Flores, Franklin Ayala & Walter H. Lewis, *Drinking the South American Hallucinogenic Ayahuasca*, 32 *Econ. Botany* 154 (1978) [Exhibit No. 10]. This article discusses the preparation of ayahuasca from the bark of *B. caapi* and other additives, and mentions its uses for treating psychological disorders.

11. Hill, Albert F., *Economic Botany: A Textbook of Useful Plants and Plant Products* 283-84 (2d ed. 1952) [Exhibit No. 11]. This textbook identifies *B. caapi* as a plant that occurs naturally in the virgin forests of the Amazon basin, and states that it is also cultivated in Indian villages and widely used in their religious ceremonies.

12. Rivier, Laurent & Jan-Erik Lindgren, "Ayahuasca," *the South American Hallucinogenic Drink: An Ethnobotanical and Chemical Investigation*, 26 *Econ. Botany* 101-03, 117 (1972) [Exhibit No. 12]. This article describes the social and medical use of *B. caapi* and ayahuasca among numerous Indian tribes living in the Upper River Purús region of southwestern Peru.

13. Schultes, Richard Evans & Albert Hofmann, *The Botany and Chemistry of Hallucinogens* 163-81 (American Lecture Series No. 1025, 1980) [Exhibit No. 13]. This monograph reviews the history of taxonomic and ethnobotanical studies of *B. caapi*, describes the use of the plant by indigenous Amazonian peoples, and provides a chemical analysis of the species' active compounds. It includes a scientific description of *B. caapi* that identifies the species' petals as "pink," and makes no mention of any yellow in them.

17. Briggs, D. & S.M. Walters, *Plant Variation and Evolution* 93-94 (1969) [Exhibit No. 14]. This text describes the phenomenon of plasticity in plants.

18. Stace, Clive A., *Plant Taxonomy and Biosystematics* 186-90 (1980) [Exhibit No. 15]. This text describes the phenomenon of plasticity in plants.

19. Stebbins, G. Ledyard, Jr., *Variation and Evolution in Plants* 72-6 (1950) [Exhibit No. 16]. This text describes the phenomenon of plasticity in plants.

C. Additional Evidence

In addition to copies of this new prior art, this Request includes the following additional evidence that helps to explain the significance of the prior art and the importance of *B. caapi* to the traditional cultures of the Requester COICA's member tribes.

1. Declaration by William R. Anderson, Director of the herbarium at the University of Michigan and a leading expert on the family of plants to which *B. caapi* belongs [Exhibit No. 17].

2. Declaration by Christine Niezgodna, Collections Manager of the herbarium of the Field Museum in Chicago, demonstrating that the above-referenced herbarium accession sheets are prior art publications under 35 U.S.C. § 102(a) and (b) [Exhibit No. 18].

3. Declaration by Antonio Jacanamijoy, General Coordinator of the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) attesting to the significance of *B. caapi* to the cultures of indigenous Amazonian peoples [Exhibit No. 19].

4. Gates, Bronwen, *Banisteriopsis, Diplopterys (Malpighiaceae)* 1, 112-14, 117 (Flora Neotropica Monograph No. 30, 1982) [Exhibit No. 20]. This is the only modern monograph on the genus to which *B. caapi* belongs. It was the sole non-patent publication cited as prior art in the Da Vine Patent application.

Additionally, a cut-up copy of the Da Vine Patent, Plant Patent No. 5,751, is attached hereto as Exhibit No. 21.

IV. SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY

The Plant Patent Act, codified in 35 U.S.C. § 161 *et seq.*, permits a patent to be awarded to any person who:

- invents or discovers and
- asexually reproduces
- a distinct and new variety of plant
- other than one found in an uncultivated state.

35 U.S.C. § 161.

The Act is designed to give patent protection to distinct and new cultivated sports, mutants, and hybrids, *Imazio Nursery, Inc. v. Dania Greenhouses*, 36 U.S.P.Q. 2d 1673, 1677; 69 F.3d 1560, 1565 (Fed. Cir. 1995), so that plant breeders have an incentive to preserve for posterity newly created plant varieties that might otherwise be lost. *Ex parte Moore*, 115 U.S.P.Q. 145, 147 (1957). The Act does not award property rights to those who discover previously unknown varieties already existing in the wild; rather, it is intended to recognize and protect inventions of the plant breeder who has worked “in aid of nature.” *See Diamond v. Chakrabarty*, 447 U.S. 303, 312 (1980) (citing S. Rep. No. 315, 71st Cong., 2d Sess., at 6-8 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess., at 7-9 (1930)).

The Plant Patent Act further states that the “provisions of [Title 35] relating to patents for inventions shall apply to patents for plants, except as otherwise provided.” 35 U.S.C. § 161. Accordingly, the provisions of 35 U.S.C. §§ 102(a)-(b), 301, and 302 pertaining to conditions for patentability, citation of prior art, and reexamination of patents are applicable to patents obtained under the Plant Patent Act.

An objective evaluation of the above-referenced prior art reveals that:

1. the claimed differences distinguishing the “Da Vine” cultivar from typical forms of *B. caapi* are either of no significance or do not exist, such that “Da Vine” is not distinct from *B. caapi* generally, and thus necessarily cannot be a new variety for the purposes of the Plant Patent Act;
2. “Da Vine” is indistinguishable from typical forms of *B. caapi* that both occur naturally in Amazonia and are cultivated by indigenous peoples there, and thus falls under the statutory prohibition against patenting wild plants;
3. issuance of the Da Vine Patent does not meet the public policy and morality aspects of the Patent Act’s utility requirement (applicable to the Plant Patent Act under its distinctness requirement), because it purports to create private

rights over the use of an entire species which forms a sacred element in the most important religious rituals of a large number of cultural and ethnic groups of South America.

Whether taken individually or collectively, these points raise substantial new questions of patentability, warranting a reexamination of Plant Patent No. 5,751.

V. DETAILED EXPLANATION OF THE PERTINENCY AND MANNER OF APPLYING THE PRIOR ART

A. The Accession Sheets Catalogued in Major U.S. Herbaria are Prior Art Publications Within the Meaning of 35 U.S.C. §§ 102 and 301

The accession sheets from herbarium collections included in this Request for Reexamination as Exhibit Nos. 1-4 are printed publications within the meaning of 35 U.S.C. §§ 102 and 301. The accession sheets are comprised of (a) dried samples of parts of plant specimens; (b) written entries that identify the collector and include his or her notes describing the plant, the date and place it was collected; and (c) notations of the date the sheet was “mounted” in the collection (i.e., cataloged and stored according to standard herbarium procedures). Scientists who use and maintain herbarium collections gather or exchange information on accession sheets in herbarium collections by examining the sheets in person or by obtaining photocopies of items such as those included with this Request. *See* Declaration of Dr. William R. Anderson ¶¶ 21-22 [Exhibit No. 17] [hereinafter Anderson Declaration]; Declaration of Christine Niezgoda ¶ 8 [Exhibit No. 18]. As is typical, photocopying services for the sheets are available at both the University of Michigan and Field Museum herbaria. *See* Anderson Declaration, *supra* Exhibit No. 17, ¶ 22; Niezgoda Declaration, *supra* Exhibit No. 18, ¶ 8.

Although there are no reported cases specifically defining the meaning of “printed publications” as they apply to prior art under 35 U.S.C. § 301, cases dealing with the identical term under the statutory bar provisions of § 102(a)-(b) clarify what materials constitute printed publications in reexamination proceedings.² Statutory bar cases are

² In fact, § 2217 of the PTO Manual of Patent Examination Procedures specifically provides that prior art applied in a reexamination request may only consist of prior art patents or printed publications that raise substantial new questions of patentability based upon the relevant portions of 35 U.S.C. § 102. Moreover, at least one court has expressly treated “printed publications” under § 301 and “printed publications” under

relevant because the underlying purpose is the same under both § 102(a)-(b) and § 301 of Title 35: to prevent “the withdrawal by an inventor, as the subject matter of a patent, of that which was already in the possession of the public.” See *In re Wyer*, 210 U.S.P.Q. 790, 793; 655 F.2d 221, 226 (C.C.P.A. 1981) (citing *In re Bayer*, 196 U.S.P.Q. 670; 568 F.2d 1357, 1359 (C.C.P.A. 1978)).

When evaluating whether a printed publication constitutes prior art under § 102, courts do not recognize a “dichotomy” between “printing” and “publication.” See *id.* (citing *Philips Electronics & Pharmaceutical Indus., Inc. v. Thermal & Electronic Indus., Inc.*, 171 U.S.P.Q. 641, 646; 450 F.2d 1164, 1170 (3d Cir. 1971)). Instead, they identify the “probability of dissemination” and the “public accessibility” of the item taken as a whole as the relevant questions. *Id.*

With respect to the “probability of dissemination,” “the traditional process of ‘printing’ is no longer the only process synonymous with ‘publication.’” *Philips*, 171 U.S.P.Q. at 646, 450 F. 2d at 1170 *quoted in Wyer*, 210 U.S.P.Q. at 793, 655 F.2d at 226. It is not necessary that multiple copies of an item have been “printed,” if there are readily available technologies for reproduction. *Id.* In *Wyer*, for instance, an application for an Australian patent was held to constitute a printed publication where it was publicly available on microfilm at the Australian Patent Office, the office had facilities for viewing and making paper copies of applications, and there was no dispute that the office had indexed and abstracted the application. *Id.* at 792.

With respect to the factor of public accessibility, dissemination by printing or other mechanical reproduction is not in itself necessary. Rather, there must be a showing that the item in some way has “been available and accessible to persons concerned with the art to which the document relates.” *Philips*, 171 U.S.P.Q. at 647, 450 F. 2d at 1171, *quoted in Wyer*, 210 U.S.P.Q. at 794, 655 F.2d at 227. Thus, the court in *Wyer* focused on whether the item had been “properly classified, indexed or abstracted” in a publicly accessible repository of information.

§ 102 as being the same. See *Freeman v. Minnesota Mining and Mfg. Co.*, 661 F.Supp. 886, 888 (D. Del. 1987) (opining that, in pending reexamination proceeding, determinative issue will be whether three printed publications in question qualify under 35 U.S.C. § 102(a) and (b) as prior publications).

Consistent with this analysis, a National Science Foundation grant proposal was considered a “printed publication” within the terms of section 102, where copies were made available to the public on request, and it was indexed by author, title, institution, and grant number. *See Du Pont de Nemours & Co. v. Cetus Corp.*, 19 U.S.P.Q. 2d 1174, 1990 U.S. Dist. LEXIS 18414 at *24 (N.D. Cal. 1990). Similarly, “a single catalogued [doctoral] thesis in one university library [constitutes] sufficient accessibility to those interested in the art exercising reasonable diligence” to qualify it as a printed publication. *See In re Hall*, 228 U.S.P.Q. 453, 455; 781 F.2d 897, 899 (Fed. Cir. 1986). A thesis open for inspection in a library is a printed publication for the purposes of Section 301, even if it may be copied only upon permission of the author and is partly handwritten, because such availability satisfies the primary purpose of making its contents known to the general public. *See Ex parte Hershberger*, 96 U.S.P.Q. 54, 56-57 (Pat. & Tr. Office Bd. App. 1952).

In light of these principles, the herbarium accession sheets attached as Exhibit Nos. 1-4 are printed publications pursuant to 35 U.S.C. §§ 102 and 301. Specimens and accompanying information in large herbaria are readily and routinely available for consultation by scientists and lay people with a legitimate need, including inspection for patent purposes. *See Anderson Declaration, supra* Exhibit No. 17, ¶ 20. The Field Museum has the world’s most prominent collections of flowering plants from Peru (one of the Amazonian countries where *B. caapi* is widely distributed) and the University of Michigan has the world’s most important collection of Malpighiaceae (the family to which *Banisteriopsis* belongs). *See Anderson Declaration, supra* Exhibit No. 17, ¶ 18; Niezgoda Declaration, *supra* Exhibit No. 18, ¶ 2. Thus, anyone “interested in the art exercising reasonable diligence,” in the words of *In re Hall*, 228 U.S.P.Q. at 455, 781 F.2d at 899, would normally visit these two herbaria if they were interested in species of Malpighiaceae. *Anderson Declaration, supra* Exhibit No. 17, ¶ 18. Both herbaria collections are cataloged by easily used systems that group the sheets first by plant family, and then alphabetically by genus and species name. *See Anderson Declaration, supra* Exhibit No. 17, ¶ 21; Niezgoda Declaration, *supra* Exhibit No. 18, ¶ 4.

In sum, a single herbarium accession sheet, like a single copy of a thesis or patent application in *Wyer, Hall* and *Hershberger*, constitutes a “printed publication” when

properly cataloged in a collection open to researchers skilled in the art, and when there is an opportunity to reproduce it. The *B. caapi* accession sheets contained in the Field Museum and University of Michigan collections and attached as Exhibit Nos. 1-4 constitute printed publications in this sense. They were accessible and available to the public in a form that guaranteed their dissemination to any persons interested in their subject matter, and for a year before Miller filed his application in November 1984. The sheets photocopied in Exhibit Nos. 2-4 were mounted and added to the herbarium collection of the Field Museum in April 1978 (Exhibit No. 2) and March 1983 (Exhibit Nos. 3-4). See Niezgoda Declaration, *supra* Exhibit No. 18, ¶ 5. The sheet photocopied in Exhibit No. 1 was mounted and added to the University of Michigan Herbarium in January 1981. See Michigan Accession Sheet, *supra* Exhibit No. 1; Anderson Declaration, *supra* Exhibit No. 17, ¶ 16. Because these sheets were printed publications in public use in the United States more than one year prior to the date of the Da Vine Patent Application, they constitute prior art under 35 U.S.C. § 102(b) and for the purposes of this Request for Reexamination.

B. Prior Art Reveals that “Da Vine” Is Neither a Distinct nor New Variety of *Banisteriopsis Caapi*

For a new variety of plant to be considered distinct under the Plant Patent Act, it must have characteristics clearly distinguishable from those of existing varieties. *Imazio Nursery*, 36 U.S.P.Q. 2d at 1677, 69 F.3d at 1565. The distinctness requirement of the Act encompasses the aggregate of the variety’s distinguishing characteristics. *Yoder Bros., Inc. v. California-Florida Plant Corp.*, 193 U.S.P.Q. 264, 291; 537 F.2d 1347, 1378 (5th Cir. 1976). It replaces the need to show an invention’s utility, which is required for obtaining non-plant patents under the Patent Act, 35 U.S.C. § 101 *et seq.* See *Yoder*, 193 U.S.P.Q. at 290, 537 F.2d at 1377. The utility requirement is nevertheless indirectly incorporated into the plant patenting process when evaluating how a plant is distinctive and new, because the characteristics that make a plant distinctive are generally recognized as the useful qualities of the new variety. See 193 U.S.P.Q. at 292, 537 F.2d at 1379. For example, a distinct and new medicinal plant can be judged by its increased or changed therapeutic value. *Id.* Similarly, a distinct and new ornamental plant can be

judged by its increased beauty and desirability in relation to other plants of its type, or by how much of an improvement it represents over prior ornamental plants. *Id.*

1. Lack of Distinctness

The Patent's claim that "Da Vine" is a new and distinct *B. caapi* plant is based on assertions covering three areas of difference: (a) usefulness of the cultivar, (b) miscellaneous morphological differences, and most importantly, (c) flower color. *See* Da Vine Patent, Exhibit No. 21, col. 1, "Summary of the Invention." None of these assertions provides a sufficient basis upon which a plant patent can be issued.

(a) Usefulness of the Cultivar

The Patent Application claims that the "new and distinct" "Da Vine" cultivar is "particularly characterized by . . . its medicinal properties." Da Vine Patent, Exhibit No. 21, abstract. The Application states that the "subject plant is being investigated for its medicinal value in cancer treatment and psycho-therapy." *Id.* It also claims that the plant has various therapeutic qualities. *Id.*

Even if "Da Vine" does have medicinal or therapeutic value, the Patent Application makes no presentment that it has any medicinal value or therapeutic qualities that are novel or distinct compared to other forms of *B. caapi*. Instead, it merely recounts qualities that traditional Amazonian healers have long known are present in *B. caapi* generally, as recounted by prior art publications. "Drug healing [with ayahuasca made from the bark of *B. caapi*] in the Peruvian jungle in many ways represents a very old and time-honoured tradition of dealing with psychological problems that predate a Freudian analysis by many centuries." Marlene Dobkin de Rios, *Ayahuasca: The Healing Vine*, 27 Int'l J. Soc. Psychiatry 256, 263 (1971) [Exhibit No. 7]. Amazonian shamans, or *ayahuasqueros* in more urbanized areas, have long used *B. caapi* to treat a wide array of organic malfunctions whose origins may be emotionally and psychologically precipitated, and that indigenous peoples often believe are related to witchcraft. *See id.* at 263-64; Marlene Dobkin de Rios, *A Note on the Use of Ayahuasca Among Urban Mestizo Populations in the Peruvian Amazon*, 72 Am. Anthropologist 1419, 1420 (1970) [Exhibit No. 5]; *see also* Marlene Dobkin de Rios, *Banisteriopsis in Witchcraft and Healing Activities in Iquitos, Peru*, 24 Econ. Botany 296 (1970) [Exhibit No. 6]; Franklin Ayala

Flores & Walter H. Lewis, *Drinking the South American Hallucinogenic Ayahuasca*, 32 *Econ. Botany* 154 (1978) [Exhibit No. 10].

Because it does not make any claim that “Da Vine” actually has any new medicinal or therapeutic value, the Patent Application relies on pure speculation that “Da Vine” might have value as a cancer treatment and in psychotherapy. But recognition of a new variety cannot be predicated on mere speculation or conjecture. *Bourne v. Jones*, 98 U.S.P.Q. 206, 209; 114 F. Supp. 413, 419 (S.D. Fla. 1952). Rather, it must be based on something ascertained, definite, and certain. *Id.* As such, the Patent Application fails to establish that “Da Vine” is in any way distinct and new from other forms of *B. caapi*, insofar as medicinal or therapeutic qualities are concerned. The existence of distinct and new medicinal value and/or therapeutic qualities thus could not have provided a basis upon which the “Da Vine” Patent was granted.³

The Patent also states that “Da Vine” “is an attractive house plant which seasonally blooms.” *Id.* A distinct and new ornamental plant is evaluated upon the degree to which its appearance differs from other plants of its type. *See Yoder*, 193 U.S.P.Q. at 292, 537 F.2d at 1379. Because the Patent does not make a case that “Da Vine” is patentable for its medicinal and/or therapeutic value, it follows that “Da Vine” is patentable only if its appearance clearly distinguishes it from that of existing varieties. *See Imazio Nursery*, 36 U.S.P.Q. at 1677, 69 F.3d at 1565. As discussed below in subsections (b) on flower petal color and (c) on claimed morphological differences, there is nothing that distinguishes the appearance of “Da Vine” as a variety from other individuals of the species *B. caapi*.

(b) Flower Petal Color

The Patent Application claims that the new and distinct qualities of “Da Vine” are “particularly characterized by the rose color of its flower petals which fade with age to near white. . .” Da Vine Patent, Exhibit No. 21, abstract. This, along with the

³ In her Monograph, Gates states that “the native populations who use this plant recognise many different kinds of *caapi*, with different hallucinogenic properties; I consider these to be chemical variants. The ease with which *caapi* can be vegetatively propagated by stem cuttings makes it possible for clones of such variants to be maintained.” Gates Monograph, *supra* Exhibit No. 20, at 114. Because the Da Vine Patent makes no assertion that Da Vine has different chemical or hallucinogenic properties than other forms of *B. caapi*, Da Vine cannot be said to be such a variant, if they in fact exist.

speculative medicinal qualities, is the most important “difference” claimed in the Patent Application. It is based on a comparison with the Gates Monograph, which describes *B. caapi* as having petals that are “pale pink, becoming pale yellow in age.” Gates Monograph, *supra* Exhibit No. 20, at 112.

Un-cited prior art available in major U.S. herbaria before the Patent Application was filed in November 1984 reveal, however, that this claimed distinction from typical forms of *B. caapi* is, in fact, non-existent. These accession sheets are summarized and analyzed in the attached Declaration of Dr. William R. Anderson, a recognized expert on the family of plants to which *B. caapi* belongs, who was Dr. Gates’ thesis advisor when she was working on her monograph. As discussed above in Section A of this Part, these sheets constitute un-cited prior art publications, raising a substantial new issue of patentability.

As Dr. Anderson explains, Dr. Gates based the observations for her Monograph upon those few specimens of *B. caapi* that were available to her at the time. These were mounted herbarium specimens containing field notes that were often of poor quality.⁴ Anderson Declaration, *supra* Exhibit No. 17, ¶¶ 2, 4, 14, 23. Dr. Gates submitted her manuscript for publication in late 1980. *Id.* at 4. Since then—but more than one year before Miller applied for the “Da Vine” Patent in November 1984—sufficient specimens with more reliable notes on flower color were catalogued in relevant herbaria collections that show that the colors given by Dr. Gates were wrong.⁵ *Id.* ¶¶ 12-15.

The most reliable observations were made by the late Dr. Timothy Plowman. *See id.* ¶¶ 13-14. Dr. Plowman’s notes, typed on the four herbarium accessioned sheets attached as Exhibit Nos. 1-4, describe flowers that are “deep pink turning white with age” (for the two specimens included as Exhibit Nos. 1 and 2); “buds deep rose pink. Petals

⁴ Dr. Anderson observes that the mounted, dried specimens available to Dr. Gates at the University of Michigan Herbarium contained varying descriptions of petal color. He speculates that the description she used in her Monograph was an attempt to deduce the natural colors from “very sketchy data.” *See* Anderson Declaration, *supra* Exhibit No. 17, ¶ 11.

⁵ As Dr. Anderson notes, the diversity of color descriptions contained in the ten collections of *B. caapi* housed at the Michigan Herbarium are “consistent in stressing that the petals in this species are pink and/or white, never yellow.” Anderson Declaration, *supra*, ¶ 14. Dr. Anderson believes Gates was “led astray by the one collection that said the petals were ‘yellow,’ which probably referred to their tendency to fade in age.” *Id.*

rose pink, the limb fading to creamy white with age, the claw remaining pale pink” (for the specimen included as Exhibit No. 3); and “buds deep rose pink. Petals rose pink, fading completely white with age” (for the specimen included as Exhibit No. 4).

These four *B. caapi* specimens were taken from cultivated vines grown from cuttings originally collected in different locations of Peru and Ecuador. *See* Collector’s Notes, Exhibit Nos. 1-4. According to Dr. Anderson, the similarity in descriptions of flower color means there can “be no doubt that Miller’s plant is identical to Plowman’s three plants.” Anderson Declaration, *supra* Exhibit No. 17, ¶ 13. The un-cited prior art publications attached as Exhibit Nos. 1-4 thus show that “Da Vine’s” “particular characteristic” of flower color is not “clearly distinguishable” from widely occurring, typical varieties of *B. caapi*, and is consequently neither distinct nor new, as required by the Plant Patent Act. *See Imazio Nursery*, 69 F.3d at 1565. This lack of distinctness raises a substantial new question of patentability.⁶

(c) Claimed Morphological Differences

The Patent Application alleges several minor ways in which the “Da Vine” cultivar differs from typical forms of *B. caapi*. Although the Abstract does not mention any of these differences as constituting the “new and distinct” characteristics of “Da Vine,” the Summary of the Invention describes them as being among the purported cultivar’s “outstanding characteristics.” They include (a) different leaf size, shape, and texture; (b) different size pedicels; (c) greater pubescence; and (d) lack of fruit (i.e., sterility). Da Vine Patent, Exhibit No. 21, col. 1, “Summary of the Invention.” They are based on comparisons between the subject plant grown by Miller in Oahu, Hawaii, and morphological observations recorded in the Gates Monograph, which the Patent cites as prior art. *Compare* Da Vine Patent, Exhibit No. 21, col. 4 *with* Gates Monograph, *supra* Exhibit No. 20, at 112-13.

These putative differences are of no significance and do not justify “Da Vine” being considered a distinct and new variety of *B. caapi*. The relevant prior art is again

⁶ It is interesting to note that Miller did not refer to the Schultes article, *supra* Exhibit No. 13, when he claimed in his patent application that “Da Vine” was particularly characterized by its flower color. That prior art includes a botanical description of *B. caapi* that refers to the plant’s petals as “pink,” and makes no mention whatsoever of them having any yellow color. *See id.* at 181.

analyzed by Dr. Anderson. First, the Gates Monograph (the sole prior art publication to which “Da Vine” was compared) was based on a limited amount of material and information. *See* Anderson Declaration, *supra* Exhibit No. 17, ¶ 2. Gates was never able to study living material of the species, so she was restricted to pressed, dried herbarium specimens. *Id.* Accordingly, the measurements contained in the Patent Application “constitute the kind of augmentation to a previous description that we expect routinely in tropical taxonomy.” *Id.* ¶ 7. They do not indicate a distinct and new variety worthy of patent recognition.

Individuals within species of plants are exceedingly variable, or “plastic,” much more so than are animals. *See id.* (citing C.A. Stace, *Plant Taxonomy and Biosystematics* 186-190 (1980) [Exhibit No. 15]; D. Briggs & S.M. Walters, *Plant Variation and Evolution* 93-94 (World U. Library, 1969) [Exhibit No. 14]; G.L. Stebbins, Jr., *Variation and Evolution in Plants* 72 *et seq.* (1950)) [Exhibit No. 16]). This is particularly so with tropical plants such as *B. caapi*. *Id.* The “Da Vine” subject plant was grown in Hawaii, rather than the Amazon lowlands where *B. caapi* is native. When a plant such as *B. caapi* is grown in different climate and soils, and under different watering regimens and light conditions, it is “to be expected that it will differ from its relatives in the original habitat and even from its parental stock.” *Id.* ¶ 8. Consequently, much of the difference relied upon by the Patent Application is likely due to growing conditions, and not to any genetically distinct or new quality of the putative variety. This observation pertains to the appearance of the leaves and pedicels, and the degree of pubescence.

Furthermore, prior art shows that most of the specimens obtained by botanists in the United States are sterile. *Id.* ¶ 3; Schultes, *supra* Exhibit No. 13, at 166 (stating *B. caapi* is incompletely known due in part to paucity of fertile collections available for taxonomic study); Gates Monograph, *supra* Exhibit No. 20, at 113 (noting that most specimens available to Gates were sterile). This may be due to a lack of the specialized, oil-gathering bees that pollinate most species of the family Malpighiaceae in their native Amazonia, or it may be that *B. caapi* is self-sterile, so that it must be cross-pollinated by a genetically distinct individual, rather than by individuals produced from cuttings of the same stock. Anderson Declaration, *supra* Exhibit No. 17, ¶ 9. Because most specimens

in the United States are sterile, the “Da Vine” cultivar’s sterility does not contribute to it being a distinct and new variety.

These facts, and the extensive overlap in Miller’s and Gates’ measurements, lead Dr. Anderson to “dismiss all those supposed differences of the claimed cultivar as utterly trivial, of no significance and quite possibly of no biological reality beyond the plasticity that characterizes plants.” *Id.* ¶ 8. Consequently, the minor morphological differences described in the Da Vine Patent do not comprise characteristics sufficiently distinguishable from those of existing varieties to be considered distinct under the Plant Patent Act. *See Imazio Nursery*, 36 U.S.P.Q. 1677, 69 F.3d at 1565. Rather, they represent an unscientific, overly “hair-splitting” approach to interpreting the Gates Monograph, which was the prior art upon which they were based.

2. Lack of Novelty

Under the Plant Patent Act, a “new” plant is one that did not exist before, rather than one that had existed in nature but was newly found. *See Yoder*, 193 U.S.P.Q. at 291, 537 F.2d at 1378 (citing *Ex parte Foster*, 90 U.S.P.Q. 16 (Pat. & Tr. Office Bd. App. 1951)). The intent of the Plant Patent Act is to recognize and protect inventions of the plant breeder who has worked “in aid of nature.” *See Diamond*, 447 U.S. at 312 (citing Senate and House of Representatives Reports). Thus, an exotic plant from a remote part of the earth that was previously unknown to United States scientists is not considered new, and is not patentable. *See Yoder*, 193 U.S.P.Q. at 291, 537 F.2d at 1378. As discussed in Section A.1 above, the claimed variety of *B. caapi* is nothing more than a typical representative of the natural species. It does not qualify as a new variety that can be the subject of a plant patent.

In fact, un-cited prior art shows that the existence of the species of which “Da Vine” is representative has long been in the public domain. In characterizing *B. caapi*, Schultes reports on scientific descriptions dating back to 1858. *See Schultes, supra* Exhibit No. 13, at 166-78. Indigenous peoples of the Amazon have widely cultivated *B. caapi* for centuries, and have long been familiar with its medicinal and psychotherapeutic properties. *See* Marlene Dobkin de Rios, *Ayahuasca—The Healing Vine, supra* Exhibit No. 7, at 256-57; Marlene Dobkin de Rios, *The Wilderness of Mind: Sacred Plants in Cross-Cultural Perspective, supra*, at 69-70 (listing Amazonian societies that use *B.*

caapi, including bibliographic references); Marlene Dobkin de Rios, *Visionary Vine: Psychedelic Healing in the Peruvian Amazon* 42 (Chandler Pub. for Health Sciences, 1972) [Exhibit No. 9] (same); Albert F. Hill, *Economic Botany*, *supra* Exhibit No. 11, at 283 (estimating that most Indian tribes of northwestern part of Amazon basin utilize *B. caapi*, which is used in religious ceremonies); *see also* Gates Monograph, *supra* Exhibit No. 20, at 113-114.

Awarding a patent to a collector who claims to discover a plant such as *B. caapi*—which in fact has been identified, collected and cultivated by indigenous Amazonians for hundred of years—does nothing to further the Plant Patent Act’s purpose of rewarding plant breeders who make new varieties available to the public, and runs counter to the need to ensure that patents augment, and do not diminish, the body of knowledge that is freely available in the public domain. Because “Da Vine” is neither new in nature nor new to the indigenous peoples of scores of tribes in Peru, Ecuador, Colombia, Bolivia, and Brazil, the patent should be canceled.⁷

The purpose of recognizing the discovery or invention of a plant is to help preserve for posterity a new variety that otherwise might be lost. *Ex parte Moore*, 115 U.S.P.Q. at 147. But granting the Da Vine Patent does nothing to preserve *B. caapi* for posterity, because “Da Vine” is not distinct from other forms of *B. caapi*, which are widely used by Amazonian peoples. Rather, the Patent simply grants Miller, its owner, a monopoly right to control the asexual reproduction of *B. caapi* throughout the United States. Un-cited prior art shows that such reproduction has been accomplished by others in this country many times before. All four of the herbarium accession sheets attached as

⁷ Analogously, the PTO has cancelled utility patent claims where a claimed invention was shown to be identical to long-held traditional knowledge, and was in the public domain and documented in past scientific publications. In 1995, researchers at the University of Mississippi Medical Center obtained a U.S. patent for the use of turmeric as a healing agent. *See Use of Turmeric in Wound Healing*, U.S. Patent No. 5,401,504, issued March 28, 1995. This patent, however, aroused considerable public controversy, because turmeric has been used to promote healing of wounds for generations by people in India. *See, e.g., India Prevents Patenting of Turmeric*, *The Statesman*, Aug. 23, 1997, available in 1997 WL 12930255; Sanjay Kumar, *India Wins Battle with USA Over Turmeric Patent*, *The Lancet* 350:724 (1997). Because the patent claims were for processes that were not new, but were part of traditional Indian knowledge in the public domain, the U.S. Patent and Trade Office canceled all six of the patent claims as a result of a reexamination requested by India’s Council of Scientific and Industrial Research. *See Use of Turmeric in Wound Healing*, U.S. Patent and Trade Office Reexamination Certificate B1 (3500th), April 21, 1998 (canceling turmeric patent claims).

Exhibit Nos. 1-4 picture *B. caapi* specimens that were taken from cultivated material. The specimens pictured in Exhibit Nos. 1 and 2 are from a plant cultivated in Miami, Florida in 1974 from a cutting gathered in Peru. See Timothy Plowman collector's notes, Exhibit Nos. 1, 2. Similarly, the specimens pictured in Exhibit Nos. 3 and 4 are from a plant grown in South Miami, Florida in August 1979 from a cutting taken in 1967 from a cultivated plant in Ecuador. See Timothy Plowman collector's notes, Exhibit Nos. 3, 4.⁸

These prior art publications containing Dr. Plowman's specimens and notes demonstrate that *B. caapi*—in a form identical to the claimed “Da Vine” cultivar—was known and used by others in this country long before the date of Miller's purported invention. Consequently, Exhibit Nos. 1-4 constitute prior art under 35 U.S.C. § 102(a), showing that “Da Vine” was not a new variety of plant as required by the Plant Patent Act, and thus raising a substantial new question of patentability.⁹

C. Prior Art Reveals that “Da Vine,” Which Is Not a Distinct Form of *B. Caapi*, Is Found in an Uncultivated State

As discussed, the Plant Patent Act provides that a patent may not be granted on a plant that is “found in an uncultivated state.” See 35 U.S.C. § 161. Wild, uncultivated varieties of plants are not patentable due to this specific statutory exclusion. See *Ex parte Foster*, 90 U.S.P.Q. 16, 17 (Pat. & Tr. Office Bd. App. 1951). The prohibition serves to exclude from the Act's scope those “wild varieties discovered by the plant explorer or other person who has in no way engaged either in plant cultivation or care and who has in

⁸ Miller's claim to have successfully asexually reproduced *B. caapi* from a cutting is not contested here. *B. caapi* is readily reproduced from cuttings. See Gates Monograph, *supra* Exhibit No. 20, at 114.

⁹ In a 1962 opinion, the U.S. Court of Customs and Patent Appeals held that a picture of a hybrid rose that appeared in a British magazine more than one year prior to the inventor's patent application did not constitute a statutory bar under 35 U.S.C. § 102(b), because it could not enable persons skilled in the art to “comprehend” how it was made. See *In re Leatrice*, 301 F.2d 929, 944 (C.C.P.A. 1962). Regardless of its legal merits, *Leatrice* is distinguished readily from the instant case. In *Leatrice*, the British photograph of the rose was not prior art because the rose itself was unavailable to persons skilled in the art. Accordingly, the photograph alone was inadequate to foreclose patentability under the statutory bar. By contrast, cuttings of *B. caapi* were available to collectors in the United States during the 1970s, as demonstrated by the collector notes contained in Exhibit Nos. 1-4. Specimens of cuttings could be viewed in major U.S. herbaria. Moreover, cuttings were available to anyone sufficiently skilled in the art who was willing to find them growing wild throughout the Amazon basin, or who was willing to obtain them from the many Amazonian peoples who grow *B. caapi*.

no other way facilitated nature in the creation of a new and desirable variety.” *Id.* at 18 (citing Senate Comm. on Patents Report, S. Rep. No. 315, 71st Cong. (1930)).

The preclusion logically extends to those plants that are found in both a cultivated and uncultivated state, such that plants that can be found both wild and cultivated are unpatentable unless the cultivated form is new and distinct from the uncultivated form. This broad preclusion is particularly important for preventing collectors from side-stepping the intent of § 161 by obtaining patents based on an application that describes an individual of a naturally occurring species that happens to have been collected, transplanted and cultivated.¹⁰

Thus, in *Foster*, the Patent Office Board of Appeals upheld the rejection of a claim that a professional plant cultivator had filed for a reputedly new variety of syngonium plant. *Id.* *Foster* had seen two syngoniums growing in a garden in Barranquilla, Colombia that appeared to be different from other syngoniums in the same garden. *Id.* at 17. The owner of the garden gave the two plants to *Foster*, which he brought back to Florida, planted, and then asexually reproduced. Relying on the legislative history of the Plant Patent Act, the Board of Appeals held that the Act does not permit the patenting of a found plant such as those discovered by *Foster*. *Id.* at 18.

Miller’s procurement of the Da Vine Patent closely parallels the facts in *Foster*. Miller obtained his cutting from a domestic garden in the Amazon rain forest. Da Vine Patent, Exhibit No. 21, col. 1, “Background of the Invention.” He made no showing that “Da Vine” is different from typical forms of *B. caapi*, other than by slight morphological differences caused by the vine’s plasticity when grown in a different environment. In her

¹⁰ Prior art shows that *B. caapi* grows wild in the Amazon region. See Schultes, *supra* Exhibit No. 13, at 181; Hill, *supra* Exhibit No. 11, at 283. It is also cultivated by the indigenous people who live there, and is grown by collectors in North America as well. See Schultes, *supra* Exhibit No. 13, at 181; Hill, *supra* Exhibit No. 11, at 283; see also Exhibit Nos. 1-4 (noting that specimens were taken from cultivated plants grown in the United States from cuttings of plants collected in South America). 35 U.S.C. § 161 precludes patentability for plants “found” in an uncultivated state, language which is most logically interpreted to preclude patenting where the variety is generally found in an uncultivated state. Consistent with this, it has been held that a patent cannot be awarded when the applicant neither has engaged in cultivation or care, nor has identified ways in which the specimen is new and different from normally occurring wild plants of the same species. See *Foster*, 90 U.S.P.Q. at 17-18. If the statutory preclusion was triggered only when the individual specimen had been found in the wild, a plant prospector could obtain a patent simply by having a third party dig up a wild plant variety and transplant it to a location where it could be “cultivated” and asexually reproduced. Such an interpretation would run counter to the purpose of the Act.

Monograph, Gates notes that it is difficult to know precisely where *B. caapi* is native, because it is widely cultivated throughout the rainforest by native populations. *See* Gates Monograph, *supra* Exhibit No. 20, at 113. Un-cited prior art shows that the species is known in the western Amazon basin both wild and cultivated in Indian garden plots. *See* Schultes, *supra* Exhibit No. 13, at 181; Hill, *supra* Exhibit No. 11, at 283. Because “Da Vine” is not distinct from typical forms of *B. caapi*, and because prior art demonstrates that *B. caapi* occurs both naturally and cultivated throughout its range, Miller’s patent is for a plant that is “found in an uncultivated state.” *See* 35 U.S.C. § 161.

Even if the garden stock from which “Da Vine” was asexually reproduced were different from *B. caapi* per se, Miller would have had nothing to do with its cultivation or care, and would have “in no other way facilitated nature in the creation of a new and desirable variety.” *Foster*, 90 U.S.P.Q. at 18; *see also* Anderson Declaration, *supra* Exhibit No. 17, ¶¶ 7, 25 (noting that, because Miller admits in the Patent Application that he has done no genetic modification to his plant, “all he has is what he started with,” which is “simply a typical representative of *B. caapi* with the flower colors accurately described”). Instead, Miller merely would have imported a “newly found variety of plant” from the rain forest, *see id.* at 17, which was precisely what was found unpatentable in *Foster*. Thus, Miller is not eligible for the benefits accruing from the award of a U.S. patent.

D. Prior Art Reveals that Issuance of the Da Vine Patent Does not Meet the Public Policy and Morality Aspects of the Patent Act’s Utility Requirement

This particular patent raises broader concerns beyond the specific questions of novelty and distinctness. These concerns fall into three categories:

1. In claiming patent rights over a plant that constitutes a sacred element in the religious traditions of many indigenous groups of the Amazon, it offends religious and moral sensibilities to an extent that is inconsistent with the concept of utility that underpins United States patent law.
2. In claiming patent rights based on supposedly distinctive pharmacological characteristics that in fact were well known to indigenous peoples living in the plant’s natural range, it wrongly appropriates traditional knowledge of indigenous and local communities. The award of patent rights over such

traditional knowledge may deprive its creators and conservators of incentives to develop, preserve and improve upon it.

3. In claiming ownership of patent rights over what in fact is a naturally occurring plant found in an uncultivated state in developing countries, it not only violates the objectives and terms of patent law, but runs counter to international principles—embodied in instruments such as the Convention on Biological Diversity—which call for the equitable sharing among countries of the benefits of the use of genetic resources.

These factors raise substantial new questions of patentability that justify reexamination. As the PTO recently noted, the utility requirement of 15 U.S.C. § 101 permits it to deny patentability to inventions deemed “injurious to the well being, good policy, or good morals of society.” United States Patent and Trade Office, *Facts on Patenting Life Forms Having a Relationship to Humans*, Media Advisory 98-6, April 1, 1998 (citing *Lowell v. Lewis*, Fed. Cas. No. 8568 (C.C. Mass. 1817) *quoted in Tol-O-Matic, Inc. v. Proma Product-und Marketing Gesellschaft, M.B.H.*, 20 U.S.P.Q.2d 1332, 1338; 945 F.2d 1546, 1552 (Fed. Cir. 1991)) [hereinafter PTO Media Advisory]. This principle extends to the patenting of plants by way of the Plant Patent Act’s distinctness requirement, which incorporates the utility requirement by recognizing that the useful qualities of a new variety are generally what make the variety distinctive. *See Yoder*, 193 U.S.P.Q. at 292, 537 F.2d at 1379.

The religious value of *B. caapi* to the indigenous peoples of the Amazon region is well documented in prior art. In the Quechua language of the Amazonian peoples of Ecuador, *B. caapi* is known as “ayahuasca”—the “vine of the souls.” *See* Laurent Rivier & Jan-Erik Lindgren, “Ayahuasca,” *the South American Hallucinogenic Drink: An Ethnobotanical and Chemical Investigation*, 26 *Econ. Botany* 101 (1972) [Exhibit No. 12]; Declaration of Antonio Jacanamijoy, General Coordinator for the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) ¶ 2 [Exhibit No. 19]. Ayahuasca has been cultivated for centuries throughout the Amazon rainforest for religious ceremonies as well as medicinal purposes. *See* Dobkin de Rios, *Ayahuasca—The Healing Vine*, *supra* Exhibit No. 7, at 256-57 (citing Schultes (1957); Cooper (1949); Karsten (1923); Spruce (1908)). “According to tradition, only shamans are authorized to

prepare the ceremonial drink made from the sacred plant, and no member of the community can drink it without the guidance of a shaman.” See Jacanamijoy Declaration, *supra* Exhibit No. 19, ¶ 4; *see also* the following prior art: Dobkin de Rios, *The Wilderness of Mind*, *supra* Exhibit No. 8, at 61, 69-70 (reviewing studies of shamanistic use of ayahuasca in Amazon and listing religious and spiritual uses of *B. caapi* by Tukano, Chama, Cashinahua, Jivaro, and Amahuaca peoples of Amazon basin); Dobkin de Rios, *Visionary Vine*, *supra* Exhibit No. 9, at 38, 45 (listing magical-religious and divination uses of *B. caapi* by Jivaro and Zaparo peoples of Ecuador as well as Mestizos of Peruvian Amazon; summarizing literature attributing religious uses of ayahuasca among the indigenous inhabitants of lowland Amazonian tropical forests). To the more than 400 cultures that populate the Amazon basin, the U.S. Patent and Trade Office’s award to Miller of property rights to *B. caapi* that allow him to commercialize a key ingredient of their religious and healing ceremonies is both incomprehensible and profoundly upsetting. See Jacanamijoy Declaration, *supra* Exhibit No. 19, ¶¶ 2-5.

Precedent for considering the religious and moral implications of intellectual property rights is found under the Lanham Act. Under 15 U.S.C. § 1052(a), trademarks can be refused or canceled if they consist of, *inter alia*, immoral or scandalous matter, or if they “disparage . . . institutions [or] beliefs, . . . or bring them into contempt, or disrepute.” Thus, registration of a trademark has been refused when it was found offensive to certain religious groups. See *In re Riverbank Canning Co.*, 37 U.S.P.Q. 268 (Cust. & Pat. App. 1938) (upholding decision of Commissioner that trademark for name “Madonna” on alcoholic beverages is scandalous); *In re P.J. Valckenberg, G.M.B.H.*, 122 U.S.P.Q. 334 (Tr. Trial & App. Bd. 1959) (same); *In re Reemtsma Cigarettenfabriken, G.M.B.H.*, 122 U.S.P.Q. 339 (Tr. Trial & App. Bd. 1959) (upholding Board’s decision that mark on cigarettes comprised of name of Moslem sect that forbids tobacco use to its followers is affront to such persons and tends to disparage their beliefs). This prohibition has extended to the commercialization of emblems that have highly sacred significance to religious groups. See *Ex parte Summit Brass & Bronze Works, Inc.*, 59 U.S.P.Q. 22 (Comm’r Pat. 1943) (denying registration of term “Agnus Dei” with picture of Agnus for use on metallic tabernacle safes).

The current practice of the Trademark Trial and Appeal Board has been to publish such marks for opposition instead of refusing outright to register them. *See, e.g., In re Mavety Media Group, Ltd.*, 31 U.S.P.Q.2d 1923; 33 F.3d 1367 (Fed. Cir. 1994); *In re Hines*, 32 U.S.P.Q.2d 1376, 1994 TTAB LEXIS 24 (Tr. Trial & App. Bd. 1994). For instance, in *Hines* the Board agreed that the use of “Budda” on beachwear that pictured Buddha wearing a bathing suit cheapens the image of the most important religious figure to Buddhists. The Board believed, however, that the legal conclusion that the trademark comprised scandalous matter would best be derived from the perspective of the group that was offended by it. *In re Hines*, 32 U.S.P.Q.2d at 1377, 1994 TTAB LEXIS 24 at *4; *see also Ritchie v. Simpson* 1999 U.S. App. LEXIS 4153 at *7-18 (Fed. Cir. 1999) (holding that person has standing to file opposition to registration when person reasonably believes he will be damaged by registration and such belief reflects real interest in issue; showing of reasonable belief is made by alleging that belief is not merely subjective but instead reflects “immutable trait or characteristic similar to that of women or Native Americans”). The Board accordingly held that the Opposition to Registration procedures of 15 U.S.C. § 1063 would provide the proper avenue for such a group to challenge the trademark registration. *Hines*, 32 U.S.P.Q.2d at 1377, 1994 TTAB LEXIS 24 at *4. By analogy, a reexamination proceeding is precisely the context in which the Commissioner may exercise his or her discretion to question a patent that is offensive to religious or moral values, particularly when those values are immutable characteristics of indigenous tribes such as those comprising the Requester in this case, COICA.

Public policy also militates against awarding patent rights based on supposedly distinctive pharmacological or psychotherapeutic characteristics that in fact were well known to indigenous peoples living in the plant’s natural range. The use of *B. caapi* for its pharmacological qualities was well documented in prior art available well before the Da Vine Patent Application was filed. Shamans prepare the liquid potion, ayahuasca, by boiling the bark of *B. caapi* for several hours and then adding other species of jungle plants. *See Flores, supra* Exhibit No. 10, at 154; Dobkin de Rios, *Ayahuasca—The Healing Vine, supra* Exhibit No. 7, at 258-59. The shamans take into consideration such things as the patient’s body weight, nature of illness, and general state of health. *See*

Ayahuasca—The Healing Vine, supra, at 258-59. For the Sharanahuas of the Purus River region near the Peruvian-Brazilian border, ayahuasca treatment by a shaman is considered the most powerful means of curing illness, particularly when other medicines fail. *See* Dobkin de Rios, *Visionary Vine, supra* Exhibit No. 9, at 47. Similarly, “belief in the efficacy of the drug healer and his powerful vine pervade all social segments of the society” of the urban poor living on the outskirts of Iquitos, Peru. Dobkin de Rios, *Ayahuasca—The Healing Vine, supra* Exhibit No. 7, at 258.

The shaman uses ayahuasca to treat a broad array of illnesses that most often approximate Western categories of psychosomatic illness. *See* Dobkin de Rios, *Note on the Use of Ayahuasca, supra* Exhibit No. 5, at 1420; Dobkin de Rios, *Visionary Vine, supra* Exhibit No. 9, at 88. These illnesses are often believed to be magical in origin, resulting from the evil will of others or else arising from punishment by a natural spirit. *Note on the Use of Ayahuasca, supra*, at 1420; *Ayahuasca—The Healing Vine, supra*, at 263-64 (naming and describing categories of illnesses found in Belen, near Iquitos, Peru, for which ayahuasca is used as treatment). The shaman does not use ayahuasca as a curative per se. Instead, he uses the potion to induce visions, which he then interprets to detect the cause of the illness and to symbolically fight it by deflecting or neutralizing the evil magic which is deemed responsible. *See* Rivier, *supra* Exhibit No. 12, at 102; Dobkin de Rios, *Ayahuasca—The Healing Vine, supra*, at 266; Dobkin de Rios, *Visionary Vine, supra*, at 45 (citing Reinburg (1921); Karsten (1923); Barret (1932); Spruce (1908); Perez de Barradas (1950); Whiffen (1915); Koch-Grunberg (1908); Harner (1968); Siskind (1970)). As these citations indicate, the unusual psychotherapeutic and pharmacological properties of substances found in *B. caapi* are well known by indigenous communities throughout the Amazon.

To award patents to individuals who merely acquire knowledge that was painstakingly accumulated and refined over generations by others would create incentives for misappropriation of information in the public domain. If traditional knowledge holders in indigenous cultures find that their knowledge can be appropriated in this way, without recognition of their contribution, the result will be to reduce incentives desperately needed for them to maintain their systems of knowledge. As many indigenous peoples inhabit the regions of the world richest in biological diversity, their

knowledge of its qualities and of practices for using it sustainably is recognized as having great value. The international community has recognized this in agreements such as the Convention on Biological Diversity, which provides that Parties to it shall protect such knowledge and practices related to biological diversity, and encourage the equitable sharing of the benefits of such knowledge.¹¹

The patent's claim of ownership of patent rights over what in fact is a naturally occurring plant found in an uncultivated state in developing countries is not only inconsistent with the objectives and terms of patent law, but also runs counter to international principles—embodied in instruments such as the Convention on Biological Diversity—which call for the equitable sharing among countries of the benefits of the use of genetic resources. The Convention creates a new international framework for access to and use of genetic resources—the ultimate source of the diversity of life on earth and an important resource for agriculture and industries such as pharmaceuticals. Each country has sovereign power over access to its genetic resources, and users outside the country are to negotiate access in exchange for sharing the benefits from their use of the resources. As has been discussed, the Da Vine Patent seeks to claim nothing more nor less than rights to the species *B. caapi*. Widespread in Ecuador and other countries in the Amazon region, the genetic information in this species constitutes a genetic resource and a natural heritage of these countries. The United States patent law was never intended to permit private intellectual property claims on such natural resources.

VI. CONCLUSION

This request for reexamination is appropriate based upon the additional prior art provided by the Requesters. For all the foregoing reasons, the Requesters believe that Claim 1 was not patentable at the time of filing, and that the Examiner would not have

¹¹ Article 8(j) of the Convention provides that each Party shall, “[s]ubject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.” Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818 (1992). Over 170 countries are Parties to the Convention. The United States has signed, but not ratified the Convention.

allowed it had the most relevant art been before him. The Requesters therefore seek a determination on the record of the validity of Claim 1.

Respectfully submitted on behalf of:

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The Coalition for Amazonian Peoples and Their Environment (Amazon Coalition).
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