

U.S. Patent and Trademark Office Reinstates Ayahuasca Patent Flawed Decision Declares Open Season on Resources of Indigenous Peoples

By Glenn Wiser, Staff Attorney, Center for International Environmental Law June 25, 2001

I. Introduction

On January 26, 2001, the U.S. Patent & Trademark Office (PTO) stunned indigenous peoples of the Amazon Basin by rescinding its earlier decision to reject a patent on the "ayahuasca" vine that had been awarded to a California entrepreneur. Loren Miller won his U.S. Plant Patent 5,751 in 1986 after he purportedly discovered a "new and distinct" variety of ayahuasca (*Banisteriopsis caapi*) growing in a domestic garden in the Amazon rainforest. Varieties of ayahuasca (also called yagé) have been known and used for centuries by shamans of indigenous tribes throughout the Amazon Basin in religious and healing ceremonies to diagnose and treat illnesses, meet with spirits, and divine the future. Indigenous peoples have characterized the plant as a religious and cultural symbol analogous to the Christian cross or Eucharist. They were profoundly disturbed that anyone, particularly an outsider, could win private property rights over a sacred plant that they had known and cultivated since time immemorial.

This issue brief analyzes the PTO's decision to reinstate the ayahuasca patent. It reviews the arguments submitted to the PTO by Loren Miller and his attorneys, and concludes that the PTO erred on issues of fact and law when it agreed with Miller. The brief particularly criticizes the PTO in Part V for applying the legal test of a plant patent *infringement* case to the reexamination procedure, when the proper test for prosecuting a reexamination is whether the subject plant is *patentable*. The brief also calls attention to the blatant double standard the PTO applied in its treatment of Miller and the indigenous peoples and environmental organizations that initiated the reexamination.

II. Victory . . . then Defeat for Indigenous Peoples

In March 1999, the Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA), the Center for International Environmental Law (CIEL), and the Amazon Alliance for Indigenous and Traditional Peoples of the Amazon Basin filed a petition requesting the PTO to cancel Miller's patent.¹ The request for reexamination included

¹ 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. CIEL is a non-profit organization that promotes sustainable and equitable development and environmental protection through the development and implementation of international law. The Amazon Alliance is an initiative born out of the partnership

several herbarium accession sheets of *B. caapi* that were available for public inspection at major U.S. botanical museums at the time Miller originally applied for his patent. COICA, Amazon Alliance and CIEL argued that the physical characteristics of the specimens in these sheets proved that "Da Vine" was neither sufficiently distinct nor new to warrant a U.S. plant patent.

The PTO agreed in an Office Action dated November 3, 1999 that the patent should never have been issued.² According to the PTO, Miller's plant, which he had dubbed "Da Vine," was not patentably distinguishable over the herbarium sheets submitted with the reexamination request. Specifically, the PTO found that the "major distinguishing feature of each of the [herbarium specimen] plants is that the flower petals are initially deep pink and turn white with age, this being the same major/distinguishing feature set forth [in Miller's patent], which [Miller] states distinguishes 'Da Vine' from all other cultivars of *Banisteriopsis caapi*."

Miller repeatedly tried over the next fourteen months to convince the PTO to reconsider its decision. Each time a filing deadline approached, Miller requested and was granted an extension of time. Then, as the extension elapsed, he filed a brief elaborating why he believed the PTO's decision to reject his patent claim was wrong.

Miller developed four basic arguments throughout these briefs. The first two dwelt upon the question of flower color, which had formed the basis for the PTO's rejection of his patent claim. Miller argued: (1) that the work of Dr. Timothy Plowman, the scientist who collected the plants mounted in the herbarium specimens and who described their flower colors, should be disregarded because it did not use "Ridgeway" color nomenclature; and (2) that a doctoral thesis published by an American scientist who had never had an opportunity to inspect live, flowering specimens of *caapi* should take precedence over Dr. Plowman's first-hand observations.

Miller's other arguments were (3) that a side-by-side comparison of one of Dr. Plowman's specimens with "Da Vine" would reveal that the leaves and stems of the two plants were dissimilar enough to justify his patent, and (4) that the difficulties Miller experienced in acquiring Plowman's specimens for physical examination were because U.S. museums had forbidden their employees to cooperate with him out of "fear of reprisals" by CIEL and COICA. Miller never explained precisely how or why a not-forprofit law firm in Washington, DC or indigenous tribes from the Amazon Basin would conspire to threaten major botanical museums throughout the United States. Indeed, we had never contacted any of the people or institutions Miller complained would not cooperate with him, with the exception of employees of one museum who had kindly helped us obtain herbarium specimen sheets when we were preparing our original reexamination request. The PTO assured us that Miller's repeated allegations were irrelevant to the reexamination process.

between indigenous and traditional peoples of the Amazon and groups and individuals who share their concerns for the future of the Amazon and its peoples.

² The PTO made this Office Action final in a subsequent Office Action dated April 14, 2000. *See* USPTO, "Office Action in Reexamination," re-exam no. 90/005307, Art Unit 1661 (Apr. 4, 2000).

Regardless of those assurances, we were entirely precluded from countering or responding to any of Miller's legal arguments. The American Inventors Protection Act of 1999 expanded the rights of "third party requesters" such as CIEL, COICA and the Amazon Alliance to participate in patent reexamination proceedings. Under the new law, third party requesters may submit a written response each time a patent owner files a brief with the PTO. However, that right applies only to proceedings for patent applications made after 1999. Because Miller applied for and received his patent before then, we were refused the opportunity to reply to any of his allegations or arguments, regardless of their merit.

The results of that exclusion were apparent when the PTO acquiesced to Miller's pleadings and issued its January 26, 2001 notice terminating the examination proceeding and reversing its earlier rejection of the "Da Vine" patent claim.³ Miller's legal strategy had had two prongs: (1) convince the PTO that the flower color descriptions in the "prior art" herbarium specimens obtained from major U.S. museums were unreliable and (2) persuade the PTO to shift its focus from "Da Vine's" flower color to the relative size and shape of its leaves. In the absence of any input from us, the strategy worked. While the PTO had based its November 3, 1999 rejection of Miller's claim nearly exclusively on its determination that "Da Vine's" flower petal color—what the patent stated to be its major distinguishing feature—was patentably indistinguishable from mounted herbarium specimens, the PTO now dismissed those herbarium specimens as inconclusive. And while the earlier rejection of the patent claim did not analyze "Da Vine's" leaf shape or size—thereby implicitly acknowledging that such characteristics alone were insufficient to make "Da Vine" patentable—now the PTO agreed that such characteristics were, in and of themselves, important enough to merit reinstatement of the claim.

The following sections of this issue brief explain why Miller's arguments were without merit, and why the PTO was wrong to accept them. Parts III and IV examine the questions of whether or not "Da Vine's" flower petal color and leaf morphology were distinct enough to entitle it to recognition under a U.S. plant patent. Part V discusses how the PTO erred when it applied the legal test of a plant patent *infringement* case to the reexamination procedure, instead of the proper test of whether the subject plant is *patentable*. Part VI discusses how the PTO disregarded the procedures it was required by law to observe in respect to Miller's efforts to convince it to reverse its decision.

III. Flower Petal Color

A. Background

In his patent application, Miller stated that "Da Vine" was a "new and distinct *Banisteriopsis caapi* plant . . . particularly characterized by the rose color of its flower petals which fade with age to near white." Miller established the patentability of his plant by contrasting his description with one contained in a 1982 monograph by Dr. Bronwen

³ See USPTO, "Notice of Intent to Issue Reexamination Certificate: Statement of Reasons for Patentability and/or Confirmation," re-exam no. 90/005307, Art Unit 1661 (Jan. 26, 2001).

Gates, which described *B. caapi* petals as "pale pink, becoming pale yellow in age." No other "prior art" was referenced in Miller's patent application, and the PTO awarded the patent on the basis of its distinctiveness from the description in the Gates monograph.

As we prepared our request for reexamination of Miller's patent, we were privileged to obtain the assistance of the Director of the Herbarium of the University of Michigan, Dr. William Anderson. Dr. Anderson is considered the world's preeminent authority on the family of plants to which the species *B. caapi* belongs. Moreover, he was Dr. Gates' thesis advisor during the time she was conducting her research and preparing her monograph.

Dr. Anderson helped us obtain dried, mounted specimen sheets of *B. caapi* from the University of Michigan herbarium and from other major U.S. botanical museums. Several of the specimens had been collected by Dr. Timothy Plowman, a botanist long noted for the accuracy of his observations. Two of those specimens—both taken from the same plant, which Dr. Plowman identified as "Martin & Plowman 1805"—contained flowers that Dr. Plowman described in his collector's notes as being "deep pink turning white with age."⁴

It was on the basis of those two specimens and the similarity of their flower color to that of "Da Vine" that the PTO granted the reexamination request and eventually rejected Miller's patent claim in November 1999.

B. Miller's response

Although Miller had elected not to participate in the proceedings when we filed the reexamination request, he responded with vigor after the PTO rejected his patent claim. His attorneys attacked the integrity of the Plowman collections by claiming that Dr. Plowman's collector's notes should be disregarded because they did not use "Ridgeway" color nomenclature and because they should be superceded by Dr. Gates' monograph. Both arguments were misleading and factually wrong. Both ultimately contributed to the PTO's final decision to restore Miller's patent.

1. "Ridgeway" color nomenclature

In his response to the PTO rejection, Miller claimed that Dr. Plowman's description of the Martin & Plowman 1805 flower color was somehow inaccurate or imprecise because it "appears not to follow standard nomenclature." He went on to state that Robert Ridgeway's 1912 *Color Standards and Color Nomenclature* "constitutes the standard for

⁴ The collector's notes are critical when evaluating flower color of herbarium sheets because the specimens lose their color when they are dried. Other herbarium sheets of specimens collected by Dr. Plowman were described as having flowers that were "rose pink, fading completely white with age." These sheets were not accepted as prior art evidence by the PTO because they were accessioned by museums in 1983—two years after Miller first filed a patent application for "Da Vine." Although Miller abandoned that application, PTO rules allowed him to "grandfather" his subsequent application, so that it was protected by the earlier date. Accordingly, the PTO only permitted CIEL, Amazon Alliance and COICA to submit prior art available from before that time to substantiate their reexamination request.

botanical flower color description." Because Dr. Plowman described his specimens as having flowers that were initially "deep pink," rather than using a "Ridgeway" term such as "deep rose pink," opined Miller, "no definable flower color can be ascertained," and the specimens should carry no evidentiary weight in evaluating whether "Da Vine" was patentable.

While Miller called upon the PTO to reject Dr. Plowman's descriptions for not precisely conforming to Ridgeway nomenclature, he simultaneously argued that Dr. Gates' description (which provided the comparative basis for his patent) should comprise the only recognized prior art, because it "uses a standard color and apparently a standard color dictionary." Strangely, Miller made this assertion despite the fact that neither the "pale pink" nor "pale yellow" of Dr. Gate's description can be found anywhere in Ridgeway. He attempted to finesse the omission by including the parenthetical reference, "see Ridgeway color 'pale pinkish buff' or 'pale pinkish cinnamon,"" in the apparent hope that those colors were somehow close enough to "pale pink" to give his inconsistent arguments credibility.

Regardless of the fact that neither the descriptions of Dr. Plowman nor Dr. Gates employed Ridgeway nomenclature, the point should have still been irrelevant, because professional plant collectors do not use Ridgeway colors. According to a declaration prepared by the University of Michigan's Dr. Anderson:

The applicant's Response to the Office Action asserts that the index from *Color Standards and Color Nomenclature* by Robert Ridgeway (1912) "constitutes the standard for botanical flower color description." My experience indicates there is no merit to that statement. I have been collecting plants for almost 40 years, and have collected with some of the best-known botanists in the world. Yet I have never known a single serious, professional plant collector who used Ridgeway colors. There are no standards for color in our field, and Ridgeway does not serve in even the smallest degree as a color standard for collectors of flowering plants. While it is true that mycologists use Ridgeway as their standard for describing colors in mushrooms, that is a different matter, because mushrooms are not plants.⁵

The PTO refused to accept a copy of Dr. Anderson's declaration. Later, in overturning its rejection and confirming the "Da Vine" patent, the PTO tacitly agreed with Miller's Ridgeway argument by stating, "for the record, it is acknowledged that the specific color designations referenced in [the "Da Vine" patent] are not set forth or otherwise specifically disclosed anywhere as being characteristic for Martin & Plowman 1805 or any other *Banisteriopsis caapi* plant per se." Where earlier the PTO had recognized that "Da Vine's" "rose fading with age to white" and the "deep pink fading with age to white"

⁵ In a later communication, Dr. Anderson adds: "I can assure you that [Dr.] Gates never consulted Ridgeway in her work, and did not quote it or intend to use its colors in her monograph. Our Herbarium's only copy of Ridgeway was stolen from our library before [Dr. Gates] ever came to Michigan. That didn't matter to the flowering plant people, but it was much lamented by the mycologists."

of the Martin & Plowman 1805 specimens were patentably indistinguishable, now the PTO examiner suggested that the standard for flower color nomenclature in reexamination procedures should be the descriptions found in color dictionaries like Ridgeway, which are not used by professional plant collectors. In so doing, the PTO further tilted the playing field against indigenous peoples who might try to protect their interests by submitting the only examples of prior art available: plant specimens housed in U.S. herbaria that were collected by scientists in the manner long practiced in their profession.

2. Reliability of the Gates monograph

In his response to the PTO's rejection of his patent and in subsequent submissions, Miller also alleged that Dr. Plowman's flower color description must be wrong because it was superceded by the Gates monograph. Miller correctly noted that Dr. Gates referred to specimens of Martin & Plowman 1805 in her monograph. He then argued that because Dr. Gates had written a description of the flower color of *B. caapi*, and because her description was based on observations of dried herbarium specimens including Martin & Plowman 1805, it followed that the difference between Dr. Gates' and Dr. Plowman's descriptions "undercut the evidentiary value" of the prior art herbarium sheets of Martin & Plowman 1805 that we had submitted and that had formed the basis for the PTO's rejection of the "Da Vine" claim.⁶

Miller's reasoning was fatally flawed for two reasons. First, in conducting her research on *B. caapi*, Dr. Gates was never able to study living material of the species. Instead, she was restricted to examining pressed, dried herbarium specimens. In describing the colors of the flower petals, she had no choice but to make do with the collectors' notes on the labels that accompanied the few flowering specimens she had access to at the time. (That information was included in the Declaration by Dr. Anderson that we submitted as part of our original reexamination request and that was accepted into evidence by the PTO. As noted earlier, Dr. Anderson had first-hand knowledge of these events because he was Dr. Gates' thesis advisor when she was researching and preparing her monograph.) By contrast, Dr. Plowman collected, propagated, and described numerous live, flowering cuttings of *B. caapi* that he personally obtained in the Amazon Basin. Dr. Plowman's knowledge of *B. caapi* flower petal color—and specifically of the Martin & Plowman 1805 specimen—was thus based on his own personal observations, while Dr. Gates had to rely on second-hand information.

Second and most important, while Dr. Gates did refer to Martin & Plowman 1805 in her monograph, the specimens she referenced were in *fruit*—they were not in flower and thus could not have formed the basis for her description of the flower color of *B. caapi*. This is clearly indicated in her citation to Martin & Plowman 1805. Inspection of Dr. Gates' citation of specimens shows that she always wrote whether a collection seen was in flower ("fl") or fruit ("fr") or both ("fl fr"). Her citation for Martin & Plowman 1805

⁶ The reader should bear in mind that specimens reproduced from cuttings are genetically identical to the parent stock. Hence, "Martin & Plowman 1805" can refer not only to the original *caapi* plant identified by Dr. Plowman, but also to cuttings taken from that plant.

reads "fr" only. The citation indicates that while she saw and identified Martin & Plowman 1805 before she published her description of *B. caapi*, the specimens she saw were in fruit, not flower.

As Dr. Gates' thesis adviser, Dr. Anderson knew she did not have access to Dr. Plowman's description of the flower petal colors until after her monograph went to press. Although Dr. Gates had seen and cited Martin & Plowman 1805 in fruit, she had no way of knowing that Dr. Plowman would soon thereafter send the University of Michigan a flowering specimen from cultivation in which he would give quite different colors from what she had put in her description.

Miller either ignored or was unaware of the elemental distinction between flowering and fruiting specimens when he submitted his allegations to the PTO. We hoped that the PTO examiners possessed the expertise to recognize this fundamental error. However, because we could not be sure, we included that information in Dr. Anderson's second declaration. As discussed earlier, the PTO refused to accept that declaration.

The PTO's apparent failure to evaluate Miller's allegations accurately may have been determinative. Before, when it rejected the patent, the PTO concluded that the major distinguishing characteristic of the herbarium specimens was their flower petal color, which was the same as "Da Vine's" major distinguishing characteristic. Now, in reinstating the patent, the PTO opined, "There is no evidence of record to indicate, let alone prove that [the herbarium specimens] are directed to . . . 'Da Vine', or even that the flower coloration . . . under consideration is identical. *Indeed the Gates Monograph* . . . *provides evidence to the contrary*" (emphasis added). Once again, without the benefit of considering a balanced presentation of the facts or opposing points of view, the PTO apparently accepted Miller's erroneous allegations at face value.

In fact, the PTO went even further by suggesting a new evidentiary standard for reexamination requesters: "No factual supporting data, *such as a comparison of the plants when grown in a side-by-side or equivalent relationship* has been brought forth by the requester to substantiate this allegation" that the flower petal color of "Da Vine" and Martin & Plowman 1805 is identical (emphasis added). Such an evidentiary standard would, of course, be impossible for requesters to meet, because the law allows them only to request reexamination on the basis of prior art "printed publications" that existed and were available to the public before the date when the patent holder applied for his patent. The PTO was very strict in applying that rule to us, and there were no opportunities to submit other forms of evidence. For the PTO later to suggest that our request for reexamination was somehow deficient because it did not include a comparison of Martin & Plowman 1805 grown side-by-side with "Da Vine"—a comparison that necessarily could not have been prepared until *after* the "Da Vine" patent had been applied for—was simply disingenuous.

IV. Leaf Shape and Size

Even though the PTO reversed course by ruling that the prior art herbarium sheets were no longer adequate, it did not make its decision to reinstate "Da Vine" on the basis of the plant's flower petal color. Instead, the PTO decided that "Da Vine" was patentable because of the size and shape of its leaves.

Miller's patent application stated that "Da Vine" was "particularly characterized" and could be "distinguished from the species per se" by its flower petal color. However, the application also suggested that various comparisons between the morphological characteristics of "Da Vine" and the description of *B. caapi* contained in the Gates monograph could help demonstrate the patentability of "Da Vine."

CIEL, COICA and Amazon Alliance argued in our request for reexamination that those supposed differences were neither sufficiently significant nor reliable to establish "Da Vine" as a new and distinct variety of *caapi* that warranted patent recognition. As Dr. Anderson explained in his first declaration included as part of the reexamination request, plants are exceedingly "plastic." When a plant is grown in a different climate, with different soils and nutrients and watering regimen and amount of light, it is to be expected that it will differ from its relatives in the original habitat and even from its parental stock. "That fact," said Dr. Anderson, "and the extensive overlap in Miller's and Gates's measurements, lead me 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. . . Except for the color of the petals [which Dr. Anderson discussed separately], there is nothing in Miller's description that sets his plant apart from the species."

The PTO apparently agreed with that analysis when it decided to reject Miller's patent claim. Stating that the major distinguishing features of "Da Vine" and the herbarium specimens were their flower petal color, and that those features were all the same, the PTO examiner's opinion concluded that "No patentable distinctions are seen between the referenced plants and "Da Vine." The examiner elected not to reference specifically the differences in leaf shape and size reported by Miller. Accordingly, his opinion implicitly ruled that those putative differences could not amount to "patentable distinctions."

After failing to convince the PTO to reverse its decision on the basis of the evidence already before it, Miller devised a new strategy. He would obtain a specimen of Martin & Plowman 1805 and pay a botanist to write up a comparison between the specimen and his "Da Vine." He would then submit the results to the PTO with the hope that the examiners would agree that the differences were substantial enough to justify his patent.

Miller had significant difficulty carrying out his plan, because most of the museums he contacted did not want to assist him in his quest to reinstate his private property rights over a plant they believed properly "belonged" to indigenous peoples or the public domain. Ultimately, however, he located a botanist at the Harvard Herbarium who had access to a specimen of Martin & Plowman 1805 and who was willing to write up a description of its measurements. Using that description, he then had a botanist in Hawaii prepare a written comparison of the Harvard specimen and "Da Vine."

After requesting and being granted numerous extensions of time, and after notifying the PTO that they intended to file an appeal of the case to the Board of Patent Appeals and Interferences, Miller's attorneys forwarded a photocopy of the Harvard specimen and description, along with a dried specimen of "Da Vine" and the comparison prepared by the Hawaiian botanist, to the PTO so that the examiner could perform his own "side-by-side" comparison of the two plants.

The Harvard specimen had no flowers. Miller's new comparison was thus based solely on the differences in the shape and size of the leaves of the two dried specimens. Despite having earlier ruled that the "major distinguishing feature" of Da Vine was its flower petal color, now the PTO took close note of the differences in the leaves. Where before, the PTO examiner had stated that the phenomenon of plasticity in plants was something the PTO should have taken into account when deciding whether "Da Vine" was patentable, now the examiner accepted Miller's logic at face value: there were some discernible differences in leaf size and shape between "Da Vine" and Martin & Plowman 1805; therefore, the specimens must not be precisely the same; therefore, even if "Da Vine" and Martin & Plowman 1805 shared the same "major distinguishing feature," Martin & Plowman 1805 could not be used to demonstrate that "Da Vine" was not new and distinct and thus not entitled to a U.S. plant patent.

V. A Crucial Misreading of the Law

The PTO examiners were able to follow that train of logic by repeatedly misreading the law and confusing the relationship between the *scope* of plant patent protection and the question of whether a plant variety was *patentable* in the first place.

In both its opinion rejecting Miller's patent claim and in its statement explaining why it was reversing that decision, the PTO referred to the 1995 *Imazio* case for the proposition that the scope of protection awarded in a U.S. plant patent is to the single germplasm of the subject plant, not to a range of plants having similar characteristics. *See Imazio Nursery v. Dania Greenhouses*, 69 F.3d 1560, 1567 (Fed. Cir. 1995). In *Imazio*, the court ruled that a plant breeder could sue for plant patent infringement only if the infringing plant was an asexual reproduction of the protected plant (i.e., if it shared the same germplasm). The plant breeder could not prove infringement merely by showing that the plant had the same essential characteristics as the patented plant. *See id.* at 1570.

The PTO examiners cited that proposition correctly. However, they erred when they extended *Imazio's* holding to an entirely different issue: the *patentability* of a plant. Under their reasoning, because *Imazio* means that plant patent protection extends only to a single germplasm and its asexually reproduced progeny, reexamination requesters can succeed in having a plant patent canceled only if they present prior art establishing that an identical plant of the same germplasm was known or used in the United States before the patent was applied for. This logic permitted the examiners to conclude that slight variations in leaf shape and size between "Da Vine" and Martin & Plowman 1805 indicated that the two plants did not share the same germplasm and were thus patentably

distinct. It also permitted them to ignore prior art and a declaration from one of the foremost experts on these plants, which had persuasively established that, compared to the leaf measurements in the Gates monograph, Miller's measurements were probably nothing more than the kind of natural augmentation one would expect to find in a tropical rainforest vine.

Imazio sets out the standard for evaluating the scope of a plant patent in an infringement case. It does not establish a standard for whether a plant patent should have been issued in the first place. That standard—*patentability*—is what a patent examiner must apply when prosecuting a patent application. Similarly, the patentability standard is what an examiner must apply in the reexamination of a plant patent.⁷

While the holding of *Imazio* goes to infringement, not patentability, *Imazio* does quote some of the legislative history pertaining to what patentability means under the Plant Patent Act:

[I]n order for the new variety to be distinct *it must have characteristics clearly distinguishable from those of existing varieties*.... The characteristics that may distinguish a new variety would include, among others, those of habit; immunity from disease; resistance to cold, drought, heat, wind, or soil conditions; color of flower, leaf, fruit, or stems; flavor; productivity, including ever-bearing qualities in case of fruits; storage qualities; perfume; form; and ease of asexual reproduction.

Imazio, 69 F.3d at 1565 (quoting S. Rep. No. 315, 71st Cong., 2d Sess. 4 (1930)) (emphasis added).

According to this legislative history, the standard for whether a plant variety is patentable—and, in turn, whether it can survive a reexamination—is whether it has "characteristics clearly distinguishable" from existing varieties. The requirement is not, as the PTO examiner mistakenly asserted, that the variety merely need be genetically distinct from other plants. Rather, it is whether its physical characteristics, including flower color, are clearly distinguishable.

Thus, in a reexamination prosecution, after a substantial new question of patentability has been raised, the patent claim must be rejected unless the plant has characteristics clearly distinguishable from existing varieties. Miller's obfuscations about "Ridgeway" color standards and the supposed preeminence of the Gates monograph notwithstanding, the Martin & Plowman 1805 herbarium specimens supplied by CIEL, COICA and Amazon

⁷ Something is patentable if it is "entitled by law to be protected by the issuance of a patent." *See* BLACK'S LAW DICTIONARY 1013 (5th ed., 1979). A plant variety is thus patentable if it satisfies the requirements of the Plant Patent Act. The purpose of a patent reexamination is to determine whether a "substantial new question of patentability" is presented, 35 U.S.C. § 303(a); in other words, whether the issuance of the patent satisfied the requirements of the Act. The reexamination may be precipitated—as the "Da Vine" reexamination was by CIEL, COICA, and Amazon Alliance—when a person cites to the PTO in writing prior art "which that person . . . believes to have a bearing on the *patentability* of any claim of a particular patent" (emphasis added). 37 C.F.R. § 1.501.

Alliance demonstrated that "Da Vine's" flower petal color—which Miller had claimed was its most important distinguishing characteristic—was not "clearly distinguishable" from all other known varieties of *B. caapi*. And as Dr. Anderson's expert testimony and the prior art on plasticity in plants revealed, the small variations in leaf size and shape between "Da Vine" and the measurements contained in a single scientific monograph could not reliably constitute "characteristics clearly distinguishable" from the species as a whole.

VI. Procedural Irregularities

The PTO's confusion between the standards for infringement and patentability allowed it to arrive at a conclusion that ran counter to the law. But Miller never would have had the opportunity to present his belated "new evidence" and arguments to the examiner had not the PTO completely disregarded the procedures it was required by law to observe.

The Code of Federal Regulations provides that, in every "ex parte" reexamination (such as the "Da Vine" proceeding), once the rejection of a patent claim is made final, then the "patent owner's reply is limited to appeal . . . or to amendment." 37 CFR § 1.113(a). The regulations contain no exceptions to that rule. The PTO made its rejection of Miller's patent claim final on April 14, 2000, after having considered and dismissed arguments Miller submitted the previous month. At that point, the restrictions of § 1.113 applied, and Miller should have been only permitted to (1) appeal the PTO's decision to the Board of Patent Appeals and Interferences or (2) amend his patent to try to render it acceptable. Yet, over the course of the next nine months, the PTO permitted him to make submission after submission of new materials and legal arguments, nearly always after granting him additional extensions of time.

First, the PTO examiner conducted a telephone interview in May with Miller's attorney, in which they discussed ways Miller might overcome the rejection. A few days later, Miller requested that, in light of the interview, he be given an extension of time to reply. That request was granted in mid-June, when the PTO examiner acknowledged that Miller would attempt to acquire descriptions of *caapi* plants that were grown under similar conditions to his "Da Vine" specimen.

In early August, Miller requested and was granted another extension, because he was having difficulty acquiring the plant descriptions. In mid-October, he submitted an additional response to the rejection, accompanied by photocopies of communications he had had with some of the botanists he had contacted on the case. He also requested an additional three-month extension and finally filed his notice of intention to appeal the PTO final action. Though the PTO denied the extension, it answered his response with an "advisory action" that made specific recommendations of how he might overcome the rejection.

That action was followed at the end of November by a request from Miller for another extension, which the PTO granted. Then, in the beginning of January 2001, Miller, thanking the PTO for its "accommodation in this matter," filed his "supplemental

response after final rejection," which included the comparison between the leaves of Martin & Plowman 1805 and "Da Vine." A few days later, he requested another onemonth extension, this time to file his appeal brief. The PTO did not respond to that request, but instead announced that it had finally been persuaded by Miller's arguments that its earlier decision was wrong and that the "Da Vine" patent should stand.

Miller filed all of these submissions after the PTO had issued its "final action" rejecting the "Da Vine" patent claim. None of these filings was an appeal or amendment to his patent. Yet the PTO accepted and carefully considered every one of them, in direct violation of § 1.113's injunction limiting Miller's permissible replies to an appeal or amendment. That willingness to accommodate Miller by treating him flexibly despite the clear terms of the law stands in stark contrast to the way COICA, CIEL and Amazon Alliance were treated when they asked for permission to submit the additional declaration from Dr. Anderson. In a letter dated May 3, 2000, the director of the Office of Patent Legal Administration indicated that, at least in the case of third-party requesters like us, the law must be applied with iron-clad rigidity: "Your request must be denied . . . Congress has spoken. Contrary to your argument, it would not be within 'the spirit of the [American Inventors Protection] Act' to *sua sponte* expand the scope of *ex parte* reexamination and permit third party participation. Such action would be in direct contradiction of expressed Congressional intent."

VII. Concluding Thoughts

The PTO "got it right" the first time when it rejected Miller's "Da Vine" patent claim. The rambling, conclusory and often circular reasoning of the examiner's statement restoring the patent does not reveal whether Miller prevailed on the basis of his arguments or simply by wearing the examiners down. Yet we do know that the playing field in this reexamination was slanted decisively toward the patent holder. Because CIEL, COICA and Amazon Alliance were completely shut out of the reexamination process once the PTO rendered its initial decision to reject Miller's patent, Miller was allowed without challenge to mischaracterize and distort relevant facts, while the PTO was able to facilitate Miller's efforts by ignoring the applicable procedural regulations and erroneously applying the law of plant patent infringement cases to the reexamination.

Ironically, Miller's protracted legal efforts left him with a patent that is economically worthless. Because the term for his "Da Vine" patent is seventeen years from the issue date of June 17, 1986, the patent will expire in less than two years, after which it will become public domain. *See* 35 U.S.C. § 154(c)(1). More importantly, the scope of protection offered by a U.S. plant patent is too narrow to give Miller anything of economic value. As articulated in *Imazio* and reiterated by the PTO, that protection extends only to the "single germplasm" contained in the patent gives Miller exclusive rights over nothing more than his original plant and specimens grown from its cuttings—it does not give him rights over any other specimens of *B. caapi*, even specimens that may be identical in appearance to "Da Vine." Miller's stated purpose in obtaining his patent was to investigate "Da Vine" for its medicinal value in cancer treatment and psychotherapy.

As there is no indication that those potential medicinal properties are unique to "Da Vine," and because the "Da Vine" patent was issued not on the basis of such properties but on the basis of its flower color, the patent gives Miller no power whatsoever to control any of the qualities that make the ayahuasca vine important to indigenous peoples or possibly commercially attractive to U.S. investors.

Still, the case remains deeply troubling for those who are concerned about the implications that U.S.-style intellectual property law may have for the preservation of biological diversity, the traditional knowledge systems of local and indigenous peoples, and other important values. Apologists for the U.S. intellectual property system often argue that the system is dynamic enough to adjust to, and accommodate, the interests of indigenous peoples. However, the behavior of the PTO demonstrates that that argument is false. The system failed those who played by the rules, as it will likely fail others in the future.

Moreover, that failure indicates a more fundamental problem. While the United Nations Convention on Biological Diversity recognizes and protects the rights of local and indigenous communities to the biological and genetic resources in their territories, the United States has never ratified the treaty. The U.S. government's failure to support it is not an anomaly. Rather, it is a reflection of the deep-seated, Western conviction that all "intellectual property" is fungible and best served by private ownership, and that non-Western knowledge systems are somehow inferior and unworthy of recognition. Reflecting that view once again, the U.S. Patent and Trademark Office has ensured that indigenous peoples—for whom "Da Vine" was not merely a silly name applied to an obscure patent, but rather a profoundly disturbing sacrilege and assault on their traditional values—are the losers.

For further information, please contact:

Glenn Wiser Staff Attorney Center for International Environmental Law 1367 Connecticut Avenue, NW Washington, DC 20036

Tel: 1-202-785-8700 Fax: 1-202-785-8701 E-mail: gwiser@ciel.org Web: www.ciel.org