

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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Ex parte MURALEEDHARAN G. NAIR and  
BOLLEDDULA JAYAPRAKASAM

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Appeal No. 2006-1245  
Application No. 10/294,106

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ON BRIEF

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Before SCHEINER, GRIMES, and GREEN, Administrative Patent Judges.  
GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to selectively inhibiting the COX-2 enzyme. The examiner has rejected the claims as indefinite and anticipated. We have jurisdiction under 35 U.S.C. § 134. We conclude that the claims are definite. However, we agree with the examiner that the claims are anticipated, although for reasons different from those advanced by the examiner. We therefore vacate the rejections based on the prior art and enter new grounds of rejection.

Background

“Cyclooxygenase-1 (COX-1) and -2 (COX-2) enzymes are responsible for the conversion of arachidonic acid, a lipid present in the cell, to prostaglandins.

Prostaglandins in turn cause inflammatory responses in the body. Inhibition of COX-1 enzyme may result in the formation of ulcers in many human[s] and hence the selective inhibition of COX-2 enzyme by compounds has a major advantage over non-selective nonsteroidal anti-inflammatory drug[s] (NSAIDs) sold over the counter (OTC).”

Specification, page 3, citations omitted.

The plant Withania somnifera, “known as Aswagandha, is well known for its use in Ayurvedic medicine. The Aswagandha root extract was reported as a folk remedy for adenopathy, arthritis, asthma, hypertension, inflammations, and rheumatism. The leaves of W. somnifera were also used as a cure for several illnesses including tumors, inflammations, conjunctivitis and tuberculosis . . . . The major chemical constituents reported from W. somnifera are called withanolides. ” Pages 1-2, citations omitted.

The specification discloses that several novel, as well as known, withanolides were isolated from the leaves of W. somnifera. Pages 7-8. A number of the isolated withanolides demonstrated the ability to selectively inhibit the COX-2 enzyme, relative to the COX-1 enzyme. Page 8. Suitable routes of administering pharmaceutical compositions containing the withanolides include oral, rectal, intraperitoneal, intranasal, subcutaneous, and intravenous. Pages 26-30.

### Discussion

#### 1. Claim construction

Claims 1, 3-5 and 10-16 are pending; however, claims 4 and 10-14 have been withdrawn from consideration by the examiner. Answer, page 2.

We note that page 2 of the Appeal Brief lists claim 4 as pending and on appeal. We also note that the Final Action of July 25, 2003, included claim 4 in the rejections set

forth therein. However, in response to a species election requirement, Appellants elected to prosecute claims directed to in vivo treatment methods. Office Action of February 10, 2003, page 4. Moreover, on page 2 of Appendix A of the Appeal Brief, Appellants provide the parenthetical descriptor “(non elected species)” with the recitation of claim 4. Thus, because claim 4 is directed to in vitro inhibition of the COX-2 enzyme, which is non-elected subject matter, claim 4 is not a part of this appeal.

Claims 1, 3, 5, 15 and 16 are therefore the subject of this appeal, and read as follows:

1. A method for selectively inhibiting COX2 enzyme relative to COX1 enzyme in a system containing the enzymes which comprises providing an effective amount of at least one withanolide selected from the group consisting of physagulin D (1→6)-β-D-glucopyranosyl-(1→4)-β-D-glucopyranoside; 27-O-β-D-glucopyranosyl physagulin D; 27-O-β-D-glucopyranosyl viscosalactone B; 4, 16-dihydroxy-5β, 6β-epoxyphysagulin D; and, 4-(1-hydroxy-2,2-dimethylcyclopropanone)-2, 3-dihydrowithaferin A so as to produce the COX2 inhibition.

3. A method for selectively inhibiting COX2 enzyme relative to COX1 enzyme which comprises providing an effective amount of at least one withanolide selected from the group consisting of physagulin D (1→6)-β-D-glucopyranosyl-(1→4)-β-D-glucopyranoside; 27-O-β-D-glucopyranosyl physagulin D; 27-O-β-D-glucopyranosyl viscosalactone B; 4, 16-dihydroxy-5β, 6β-epoxyphysagulin D; and, 4-(1-hydroxy-2,2-dimethylcyclopropanone)-2, 3-dihydrowithaferin A in a pharmaceutically acceptable carrier in vivo to a mammal in need thereof so as to produce the COX2 inhibition.

5. The method of claim 1 wherein the inhibition is in vivo in a mammal.

15. A method for selectively inhibiting COX2 enzyme relative to COX1 enzyme which comprises providing an effective amount of a compound selected from the group consisting of compounds physagulin D (1→6)-β-D-glucopyranosyl-(1→4)-β-D-glucopyranoside; 27-O-β-D-glucopyranosyl physagulin D; 27-O-β-D-glucopyranosyl viscosalactone B; 4, 16-dihydroxy-5β, 6β-epoxyphysagulin D; and, 4-(1-hydroxy-2,2-dimethylcyclopropanone)-2,3-dihydrowithaferin A; and, mixtures thereof and a compound selected from the group consisting of 2, 3-dihydrowithaferin A; viscosalactone B; 23, 24-dihydrowithaferin A; sitoindoside IX; physagulin D; withanoside IV; withaferin A;

and, mixtures thereof to a system containing the enzymes so as to produce the COX2 inhibition.

16. A method for selectively inhibiting COX-2 enzyme relative to COX-1 enzyme in vivo in a mammal in need thereof which comprises providing an effective amount of an isolated withanolide with the enzyme in the mammal so as to produce the COX-2 inhibition.

Thus, claims 1, 3 and 5 are directed to selectively inhibiting the COX-2 enzyme relative to the COX-1 enzyme, by administering an effective amount of one or more of five specific withanolides. Claims 3 and 5 require the inhibition to be in vivo, the species of inhibition elected by Appellants for prosecution, and in a mammal. Claim 3 requires the additional presence of a pharmaceutically acceptable carrier in the therapeutic composition.

Claim 15 is directed to inhibiting the COX-2 enzyme relative to the COX-1 enzyme, by administering an effective amount of one or more of the five withanolides enumerated in claims 1 and 3, along with one or more of seven distinct withanolides also enumerated in the claim.

Claim 16 is directed to inhibiting the COX-2 enzyme relative to the COX-1 enzyme, in vivo in a mammal, by administering an effective amount of an isolated withanolide to the mammal.

All of the claims on appeal require administering “an effective amount” of the claimed withanolides, “so as to produce the COX[-]2 inhibition.” As is evident, none of the appealed claims recites specific empirical dosages which would guide us to a precise meaning for the term “effective amount.” However, “[i]t is axiomatic that, in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification and that claim language

should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.” In re Sneed, 710 F.2d 1544,1548, 218 USPQ 385, 388 (Fed. Cir. 1983) (citation omitted).

The specification states that “[i]n pharmaceutical compositions, the withanolide is inhibitory at a dosage of 1 to 1,000 micrograms per milliliter or gram.” Specification, page 26, lines 5-7. Therefore, we construe the “effective amount” recited in the claims to encompass a composition containing as little as one microgram per gram of any one of the withanolides recited in the claims. That is, any composition having as little as one microgram of the claimed withanolides, per gram of total composition weight, would appear to meet the limitation requiring “an effective amount” of the claimed withanolides “so as to produce the COX[-]2 inhibition.”

## 2. Definiteness

The examiner rejected claims 1, 3, 5, 15 and 16, under 35 U.S.C. § 112, second paragraph, on the basis that the claims were indefinite because they failed to particularly point out and distinctly claim the subject matter regarded by Appellants as being the invention. The examiner’s rationale for the rejection appears in its entirety as follows:

It is not clear if the plant extract is being administered to the patient or subject. Appellant[s] need [ ] to explicitly state that the plant extract is administered to the patient or subject in need thereof.

Further, the statement “in a system containing the enzymes[,]” is confusing. It would be clearer if [A]ppellant[s] stated that the system is a subject such as a mammal thus it would be clearer if [A]ppellant[s] amended the claims to read that the withanolide is administered to a patient in need thereof.

Answer, page 4.

Appellants argue that the claim language directs the practitioner to administer the claimed compounds to the subjects of the claims. Brief, page 16. Appellants further argue that specification discloses the administration of individual compounds obtained from the plant, as well as combinations thereof. Id., at pages 16 and 17. Appellants further urge that the language “in a system containing the enzymes” encompasses both in vivo and in vitro systems, which are both supported by the disclosure in the specification.

To the extent they argue that the claims are definite, we agree with Appellants. Specifically, 35 U.S.C. § 112, second paragraph, requires only that one of skill in the art, reading the claims in light of the specification, be able to clearly distinguish between subject matter encompassed by the claims, and subject matter not encompassed by the claims. See Miles Laboratories Inc. v. Shandon Inc., 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993) (“The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification.”). Thus, “[t]he purpose of claims is not to explain the technology or how it works, but to state the legal boundaries of the patent grant. A claim is not ‘indefinite’ simply because it is hard to understand when viewed without benefit of the specification.” S3 Incorporated v. NVidia Corp., 259 F.3d 1364, 1369, 59 USPQ2d 1745, 1748 (Fed. Cir. 2001).

We acknowledge that the language “providing” might not be the most commonly used terminology in claims directed to in vivo treatment methods. However, all of the claims require the inhibitory withanolides to be “provid[ed] . . . so as to produce the COX[-]2 inhibition.” In our view, given the dependent claims specifically directed to in

vivo inhibition, and reading the claims in light of the specification, it is sufficiently clear that one must administer the recited withanolides to a patient or subject to achieve inhibition.

Similarly, the claims are not indefinite because they recite, at their broadest, providing the withanolides to “a system containing the enzymes.” As stated in In re Miller, 441 F.2d 689, 693, 169 USPQ 597, 600 (CCPA 1971), “breadth is not to be equated with indefiniteness.” Thus, the fact that the language “system containing the enzymes” is broad does not mean that the language is indefinite. In our view, it is clear from the claims and specification that the term “system” encompasses any system that contains the two enzymes, including in vivo systems, such as mammals, as well as in vitro systems. We therefore reverse the rejection under 35 U.S.C. § 112, second paragraph.

However, we do not agree with Appellants’ argument that the transitional phrase “consisting of,” present in the Markush language “selected from the group consisting of” in claims 1, 3 and 15, excludes from those claims all “materials other than those recited except for impurities ordinarily associated therewith.” Brief, page 17.

Specifically, the preambles of claims 1, 3 and 15 each recite “[a] method . . . which comprises . . . .” (Emphasis added.) As stated in Gillette Co. v. Energizer Holdings Inc., 405 F.3d 1367, 1371, 74 USPQ2d 1586, 1590 (Fed. Cir. 2005), “[t]he word ‘comprising’ transitioning from the preamble to the body signals that the entire claim is presumptively open-ended.” Moreover, “[t]he transition ‘comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps.” Invitrogen Corp. v. Biocrest Manufacturing L.P., 327 F.3d 1364, 1368, 66 USPQ2d

1631, 1634 (Fed. Cir. 2003). Thus, the word “comprises” in the preambles of Appellants’ independent claims signifies that the claims encompass subject matter containing not only the elements required by the claims, but also elements not recited in the claims. See Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“‘Comprising’ is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.”).

The phrase “consisting of,” within the Markush terminology “selected from the group consisting of,” limits the Markush groups of claims 1, 3 and 15 to the members set forth within the group. See Gillette v. Energizer, 405 F.3d at 1372, 74 USPQ2d at 1590 (“A Markush group by its nature is closed.”). However, as discussed above, the preamble of every independent claim on appeal herein contains the open term “comprises,” which does not exclude the presence of additional elements or process steps. Genentech v. Chiron, *supra*. Thus, contrary to Appellants’ argument (Brief, pages 17-18), the “consisting of” language in the Markush group descriptor does not serve to limit the claims to the administration of only the named withanolides, to the exclusion of any ingredient other than impurities normally associated with those compounds. See Mannesmann Demag Corp. v. Engineered Metal Products Co., Inc., 793 F.2d 1279, 1282, 230 USPQ 45, 46 (Fed. Cir. 1986) (holding that an element within the body of a claim using the term “consisting of” did not limit an entire claim containing the term “comprising” in the transition from the preamble to the body of the claim).

To summarize, we agree with Appellants that the appealed claims are definite. We therefore reverse the rejection under 35 U.S.C. 112, second paragraph. However,

we do not agree with Appellants that the claims exclude the presence of ingredients not recited in the claims.

### 3. Anticipation rejections on appeal

The examiner also rejected claims 1, 3, 5, 15 and 16 under 35 U.S.C. § 102(b) as being anticipated by Tomi,<sup>1</sup> Kashinath,<sup>2</sup> Takatori,<sup>3</sup> Ota,<sup>4</sup> Att-ur-Rahman,<sup>5</sup> Patwardhan,<sup>6</sup> Chavali,<sup>7</sup> Matsuda,<sup>8</sup> Thakur,<sup>9</sup> or Anjaneyulyu,<sup>10</sup> and under 35 U.S.C. § 102(a) as being anticipated by Kameyama.<sup>11</sup>

The examiner reasoned that

[t]he references each teach that an extract from Withania somnifera is administered to a patient. The plant extract of the references inherently contains the withanolide since it is simply an extract of the claimed plant. The claims encompass using the same extract which will inherently contain the same components since it is the same exact plant extract that [A]ppellant[s] used in [their] invention. Thus, the claims are anticipated by the cited references.

Answer, page 5. The examiner's rationale for the rejection under § 102(a) is substantially identical. Id.

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<sup>1</sup> Tomi et al., WO 00/67768, published November 16, 2000 (English equivalent U.S. Patent 6,866,872, issued March 15, 2005).

<sup>2</sup> Kashinath, ZA 9500908, published December 27, 1995. This document was provided as a Derwent abstract only, as the USPTO library was unable to obtain a copy of the entire reference, despite contacting the South African patent office. See Office Letter mailed January 4, 2006.

<sup>3</sup> Takatori, JP 10-36216, published February 10, 1998.

<sup>4</sup> Ota et al., JP 2001-58951, published March 6, 2001.

<sup>5</sup> Atta-ur-Rahman et al., "Two New Withanolides from Withania Somnifera," Heterocycles, Vol. 34, No. 4, pp. 689-698 (1992).

<sup>6</sup> Patwardhan, U.S. Patent 5,494,668, issued February 27, 1996.

<sup>7</sup> Chavali et al., U.S. Patent 5,683,698, issued November 4, 1997

<sup>8</sup> Matsuda et al., "Structures of Withanosides I, II, III, IV, V, VI and VII, New Withanolide Glycosides, from the Roots of Indian Withania Somnifera DUNAL. and Inhibitory Activity for Tachyphylaxis to Clonidine in Isolated Guinea-Pig Ileum," Bioorganic & Medicinal Chemistry, Vol. 9, pp. 1499-1507 (2001).

<sup>9</sup> Thakur et al., Major Medicinal Plants of India, Central Inst. of Medicinal and Aromatic Plants, Lucknow, India, pp. 531-535 (1989).

<sup>10</sup> Anjaneyulyu et al., "A new withanolide from the leaves of Withania somnifera," Indian Journal of Chemistry, Vol. 36B, pp. 161-165 (1997).

<sup>11</sup> Kameyama et al., JP 2002-145794, published May 22, 2002.

In response, Appellants only argue that none of the references teaches the claimed methods. Brief, pages 19-24. Appellants do not offer any rationale for this conclusion, for example, by providing a factual basis as to why the examiner's holding of inherency is incorrect.

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Thus, "a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it." Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1946 (Fed. Cir. 1999). One of ordinary skill viewing the reference need not recognize the inherent properties disclosed by the reference. Id., at 1347, 51 USPQ2d at 1947. ("Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.") (citations omitted).

To establish that a reference inherently discloses a specific limitation, the examiner may refer to extrinsic evidence demonstrating that the descriptive matter missing from the reference is necessarily present in the reference's disclosure. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). ("To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill."). Thus, the examiner cannot establish

inherency merely by demonstrating that the asserted limitation is probable or possible. In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (“The mere fact that a certain thing may result from a given set of circumstances is not sufficient [Citations omitted.] If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.”) (quoting Hansjorg v. Kemmer, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939) (emphasis and bracketed material in original)).

With these principles in mind, we believe that there are serious questions with respect to the prima facie case of anticipation advanced by the examiner. Directly contrary to the examiner’s assertion that “an extract from Withania somnifera is administered to a patient” (Answer, page 5), at least two of the cited references simply do not disclose the administration of W. somnifera extracts to patients. See, e.g., Attaur-Rahman, (page 689, disclosing the “medicinal interest” of the plant, with no mention of administration of any “extract” to a patient); see also Kashinath (no mention of the word “extract” in the abstract provided).

Moreover, regarding those references actually disclosing administration of extracts, the examiner does not refer to any extrinsic evidence explaining why the prior art extracts, made from different parts of the plant, using solvents different than used in Appellants’ specification, would necessarily contain the claimed withanolides. In our view, because the cited references disclose a number of distinct extracts prepared from different parts of the plant, using a variety of different solvents and fractionation techniques, the simple assertion that the prior art extracts are from “the same exact

plant” (Answer, page 5), fails to establish inherency, without further explanation or evidence. Conversely, as noted supra, Appellants’ response does not explain why the references do not inherently disclose the withanolides.

In our view, neither the examiner nor Appellants have recognized the full breadth of the claims. We therefore vacate the examiner’s rejections and enter the following new grounds of rejection.

#### New Grounds of Rejection

##### 1. Anticipation of claims 1, 3, 5 and 15

Under the provisions of 37 CFR § 41.50(b), we enter the following new ground of rejection: claims 1, 3, 5 and 15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Thakur.

As discussed supra, claims 1, 3 and 5 are directed to selectively inhibiting the COX-2 enzyme relative to the COX-1 enzyme, by administering an effective amount of one or more of five specific withanolides. Claims 3 and 5 require the inhibition to be in vivo, and in a mammal. Claim 15 is also directed to inhibiting the COX-2 enzyme relative to the COX-1 enzyme, by administering an effective amount of one or more of the five withanolides enumerated in claims 1 and 3, along with one or more of seven distinct withanolides also enumerated in the claim.

Appellants isolated the five withanolides recited in the first Markush group in claims 1, 3 and 15, from the leaves of W. somnifera. Specification, pages 8-9. Therefore, any prior art disclosure of unfractionated leaves of W. somnifera necessarily, or inherently, discloses a composition which contains the five withanolides recited in claims 1, 3, 5 and 15. Moreover, because the leaves are part of the plant, any

unfractionated plant or preparation thereof also inherently contains the five withanolides recited in the first Markush group. Further, we note that the specification states, at page 17, lines 1-7, that “[s]ince both roots and leaves of W. somnifera contain similar withanolides, consumption of W. somnifera root powder or leaf extract as a dietary supplement can decrease the inflammatory pain, the risk of cancer formation and progression of tumors at levels which suppress the COX-2 enzyme.” Based on this evidence, one of ordinary skill would have concluded that unfractionated preparations of leaves, roots, or the entire plant, inherently contained the claimed withanolides.

The COX-2 enzyme is active in inflamed tissue, such as that of arthritic patients. University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 917, 69 USPQ2d 1886, 1888 (Fed. Cir. 2004) (“COX-2 is expressed in response to inflammatory stimuli, and is thought to be responsible for the inflammation associated with diseases such as arthritis.”). COX-2 enzyme is also active “not only in inflamed cells[,] but also [in] various tumor cells.” Specification, page 3, lines 14-16.

Based on the analysis above, Thakur’s disclosure of the therapeutic uses of W. somnifera provide a number of instances wherein the recited withanolides were inherently provided to a mammal.

Specifically, Thakur discloses that “Ashwagandha is a folk remedy for . . . arthritis . . . inflammation . . . rheumatism.” Thakur, page 531, right column. “For . . . inflammations and swellings, the leaves are applied steeped in warm castor oil. Leaf juice is useful in conjunctivitis.” Id. “In Ayurveda, leaves are used in treating tumors . . . and the roots . . . [are] useful in . . . inflammations . . . .” Id., at page 532, left column. “In Unani, the roots are used in . . . inflammations [and]. . . arthritis . . . .” Id. “Powdered

roots of the plant exhibit antiinflammatory activity.” Id., at page 534, right column. “The plant also inhibited antiinflammatory and antitumor activities.” Id., citations omitted.

Thus, Thakur discloses that the whole plant, leaves, or roots of W. somnifera have been administered to treat pathogenic conditions in which COX-2 is active. Because the whole plant, leaves and roots inherently contain the claimed withanolides, Thakur discloses that the claimed withanolides have been administered to treat pathogenic conditions where COX-2 is active. Regarding the requirement in claim 3 of a pharmaceutically acceptable carrier, we note that any of the non-withanolide ingredients present in Thakur’s leaf, root, or whole-plant preparations can properly be considered a carrier.

Based on the evidence before us, Thakur also discloses that the claimed withanolides were administered in amounts effective to selectively inhibit COX-2. Specifically, Appellants’ specification discloses the percentages of the claimed withanolides within dried leaves. Specification, page 17, lines 21-22 (“Yields of the withanolides are expressed in percentage dry weight of the leaves.”).

Compounds “1” through “5” correspond to the five withanolides recited in claims 1 and 3, and the first Markush group in claim 15. Specification, page 8, lines 5-15. The concentrations of the claimed withanolides, based on the dry weight of leaves are:

0.0068% for compound 1 (Specification, page 19, lines 3-4),

0.0078% for compound 2 (page 18, lines 26-27),

0.0055% for compound 3 (page 19, line 1),

0.0032% for compound 4 (recovered as a mixture with compound 12, page 19, lines 4-5), and

0.0065% for compound 5 (page 18, line 24).

These percentages can be converted to micrograms per gram, the units used by Appellants to describe the “effective amount” limitation:<sup>12</sup> compound 1 is present in dry leaves at 68 micrograms per gram, compound 2 at 78 micrograms per gram, compound 3 at 55 micrograms per gram, compound 4 at 32 micrograms per gram, and compound 5 at 65 micrograms per gram.

As discussed supra, the specification states that compositions having as little as one microgram of the claimed withanolides per gram of total weight will selectively inhibit COX-2. Specification, page 26, lines 5-7. Thus, dried leaves of W. somnifera inherently contain concentrations of the claimed withanolides ranging from 32 times, to as high as 78 times, the concentration required to induce selective inhibition of COX-2.

This evidence provides ample reason to believe that the leaf, root, and whole plant preparations, disclosed by Thakur as being administered to treat inflammatory disorders, inherently meet the claim limitation requiring administration of an amount of the claimed withanolides effective to inhibit COX-2. The therapeutic benefits, disclosed by Thakur, of the W. somnifera preparations on inflammatory disorders including arthritis and conjunctivitis, provide additional evidence that the claimed withanolides are present in the whole plant, leaves and roots, in concentrations sufficient to selectively inhibit COX-2.

Therefore, based on Thakur’s disclosure of using therapeutic compositions inherently containing the claimed withanolides to treat inflammatory conditions,

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<sup>12</sup> 1% by weight is equal to 1 gram per 100 grams of leaves, so 0.001% is equal to 1 milligram per 100 grams of leaves, or 10 micrograms per gram of leaves.

combined with the very low threshold concentration required to induce inhibition, we find that Thakur inherently provides the claimed withanolides to a mammal in amounts effective to selectively inhibit COX-2. Thakur therefore anticipates claims 1, 3, 5, and 15.

To summarize, “a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it.” In re Cruciferous Sprout Litigation, 301 F.3d 1343, 1349, 64 USPQ2d 1202, 1206 (Fed. Cir. 2002). Moreover, “the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer. . . . This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art.” Atlas Powder, 190 F.3d at 1347, 51 USPQ2d at 1947 (emphasis added). Thus, the fact that Appellants may have recognized novel compounds within prior art W. somnifera compositions cannot render methods of using those compositions patentable, when the prior art discloses using compositions encompassed by the claims according to the claimed steps. See Cruciferous Sprout, 301 F.3d 1343, 64 USPQ2d 1202 (claims to therapeutic methods of administering sprout compositions held anticipated due to inherent presence of claimed therapeutic agent therein).

Lastly, we note that “where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.” In re Swinehart, 439 F.2d 210,

212-13, 169 USPQ 226, 229 (CCPA 1971); accord, In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (“[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.”). Thus, “[i]n response to the PTO’s asserted prima facie case the applicant may argue that the inference of lack of novelty was not properly drawn, for example if the PTO did not correctly apply or understand the subject matter of the reference, or if the PTO drew unwarranted conclusions therefrom.” Spada, 911 F.2d at 708, 15 USPQ2d at 1658.

On the current record, Appellants’ sole argument against the Thakur reference as applied by the examiner is simply that the reference does not disclose the claimed process. Thus, Appellants do not provide any specific argument or evidence rebutting the fact-based conclusion discussed supra, that the therapeutic methods disclosed by Thakur meet the limitations of claims 1, 3, 5 and 15. We therefore reject claims 1, 3, 5 and 15 as anticipated by Thakur, for the reasons set forth supra.

## 2. Anticipation of claim 16

Under the provisions of 37 CFR § 41.50(b), we enter the following new ground of rejection: claim 16 is rejected under 35 U.S.C. § 102(b) as being anticipated by Patwardhan.

Claim 16 recites a process of selectively inhibiting COX-2, relative to COX-1, by administering least one “isolated” withanolide, in an amount effective produce the COX-2 inhibition.

Patwardhan discloses the administration of a composition comprising an extract of W. somnifera for the treatment of rheumatoid arthritis and osteoarthritis. Abstract.

As discussed supra, arthritis is an inflammatory condition in which COX-2 is active.

Patwardhan also teaches that the described therapeutic extract of W. somnifera contains withanolides. Column 5, lines 13-25 (“Chemical constituents include . . . steroidal glycosides (sitoindosides and withanolides). Withaferin A is the most important of the withanolides. Sitoindosides and Withanolides are together mainly responsible for the biological activity of Ashwagandha . . .”).

Patwardhan therefore discloses the administration of a composition comprising withanolides, including one of those purified by Appellants from leaves (Withaferin A; see Specification, page 8, lines 15-16), to a patient to treat a condition whereby COX-2 is active.

With respect to the requirement that the withanolide be “isolated,” we note that, for examination purposes, claims must be construed as broadly as reasonable, in a manner consistent with the specification. Sneed, 710 F.2d at 1548, 218 USPQ at 388. At its broadest, the term “isolated” requires only that the withanolide be isolated from something. Through the extraction process, the withanolides within Patwardhan’s extract have necessarily been isolated from a number of the ingredients originally present in the plant. The withanolides within Partwardhan’s extract therefore meet the limitation that they be “isolated.”

Lastly, the therapeutic effect of the disclosed extract demonstrates that Patwardhan’s composition contained an isolated withanolide in an amount effective to selectively inhibit COX-2. This is especially true in view of the disclosure in Appellants’

specification that as little as one microgram of withanolide per gram of composition is sufficient to induce selective inhibition. Specification, page 26, lines 5-7. Based on these facts, we hold that Patwardhan anticipates claim 16.

#### Summary

We reverse the rejection for indefiniteness and vacate the examiner's rejections based on the prior art. We also enter two new rejections based on anticipation. We have considered the arguments in the Appeal Brief, but do not find them persuasive with respect to the new grounds of rejection.

#### Time Period for Response

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner . . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record . . . .

REVERSED, 37 CFR § 41.50(b)

Toni R. Scheiner	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
Eric Grimes	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
Lora M. Green	)	
Administrative Patent Judge	)	

EG/FP/jlb

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