



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PAUL J. BOBROWSKI

Appeal 2008-0580
Application 10/679,006
Technology Center 1600

Decided: March 31, 2008

Before RICHARD TORCZON, SALLY G. LANE, and JAMES T.
MOORE, *Administrative Patent Judges*.

MOORE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF CASE

The Appellant appeals under 35 U.S.C. § 134 (2002) from a final rejection of claims 10, 12-15, and 19-24.¹ We have jurisdiction under 35 U.S.C. § 6(b) (2002).

¹ Claims 1-9 have been withdrawn from consideration as directed to a non-elected invention. *See* Non-final Rejection, Sep. 8, 2005 (restriction requirement). Claims 11 and 16-18 have been canceled.

The Appellant's claims are directed to pharmaceutical preparations for the treatment of itch, nausea, hyperalgesia and the complications of opioid agonists. Claims 10 and 13 are the only independent claims in the application. Claims 10 and 13 read as follows:

10. An extract of plant material from family Euphorbiaceae and species Croton that reduces at least one opioid-induced complication selected from the group consisting of; [sic] nausea, emesis, retching and itch, the extract at a concentration of 1 mg/mL of 50% (v/v) ethanol/water having reduced UV absorbency of about at least 4.3 between the range of 390 nm and 430 nm relative to the absorbency within the same range for unextracted plant material.

13. An extract of plant material from species Croton family Euphorbiaceae that reduces the effect of hyperalgesia, and which at a concentration of about 1 mg/mL of carrier has a reduced UV absorbency in the range of 390 nm and 430 nm of at least 4.3 relative to the same concentration of unextracted plant material in the same carrier.

THE REJECTIONS

The Examiner relies upon the following as evidence in support of the rejections:

Persinos	US 3,809,749	May 7, 1974
Nilubol	US 5,264,638	Nov. 23, 1993
Zaveri	US 5,957,437	Sep. 28, 1999
Kashide I	JP 52070010	Jun. 10, 1977
Kashide II	JP 52144665	Dec. 2, 1977
Kawamori	JP 07010777	Jan. 13, 1995
Nagaho	JP 410231239	Sep. 2, 1998
Ota	EP 0897712	Feb. 24, 1999
Yagi	JP 411139952	May 25, 1999
Tsuchizaki	JP 12336024	Dec. 5, 2000
Fankhauser	US 20020155073 A1	Oct. 24, 2002

The following rejections are before us for review:

1. Claims 10, 12, 13, 15, and 19-24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Persinos.
2. Claims 10, 12, 13, 15, 19-22, and 24 stand rejected under 35 U.S.C. § 103(a) over Kashide I (JP52070010), Kashide II (JP52144665), Kawamori, or Nilubol.
3. Claims 13-15, 19-22, and 24 stand rejected under 35 U.S.C. § 103(a) over the combination of Tsuchizaki, Ota, Nagano or Yagi with either Zaveri or Fankhauser.
4. Claims 13-15 and 19-22 stand rejected under 35 U.S.C. § 103(a) over the combination of Persinos with either Zaveri or Fankhauser.
5. Claims 10, 12, 13, 15, 19-22, and 24 stand rejected under 35 U.S.C. § 103(a) over the combination of Persinos with either Kashide I (JP 52070010), Kashide II (JP 52144665), Kawamori, or Nilubol.

We REVERSE *pro forma* and enter a new ground of rejection under 35 U.S.C. §112, second paragraph, for independent claims 10 and 13, and their dependent claims.

ANALYSIS

The appellant's claims do not particularly point out and distinctly claim the subject matter. Because the appealed claims fail to satisfy the requirements of the second paragraph of 35 U.S.C. § 112, we do not reach the merits of the Examiner's rejections under 35 U.S.C. § 102 or § 103 at this time. To that end, the predecessor of our reviewing court has held that it is erroneous to analyze claims based on "speculation as to the meaning of the terms employed and assumptions" as to their scope. *In re Steele*,

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305 F.2d 859, 862, 1300 (CCPA 1962) (“We do not think a rejection under 35 U.S.C. § 103 should be based on such speculations and assumptions.”).

Claims 10 and 13 are newly rejected under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. (37 C.F.R. § 41.50(b)).

“[T]he definiteness of the language employed must be analyzed – not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art.” *In re Moore*, 439 F.2d 1232, 1235, 1047 (CCPA 1971).

One of ordinary skill, as understood from the art of record, would have experience formulating topical pharmaceutical compositions (Persinos 1:13-15), such that he or she would be familiar with blending (*Id.* 2:19-56), incorporating effective amounts (*Id.* 3:63 et seq.), and making creams, lotions, oils, aerosols (*Id.* 6-7) and testing for efficacy (*Id.* 8-10).

We now turn to the claims at issue.

Claim 10 reads as follows:

An extract of plant material from family Euphorbiaceae and species *Croton*

(1) that reduces at least one opioid-induced complication selected from the group consisting of; nausea, emesis, retching and itch,

(2) the extract at a concentration of 1 mg/mL of 50% (v/v) ethanol/water having reduced UV absorbency of about at least 4.3 between the range of 390 nm and 430 nm relative to the absorbency within the same range for unextracted plant material.

(Indenting and numbering added).

Claim 13. An extract of plant material from species Croton family Euphorbiae
(1) that reduces the effect of hyperalgesia, and which
(2) at a concentration of about 1mg/mL of carrier has a reduced UV absorbency in the range of 390 nm and 430 nm of at least 4.3 relative to the same concentration of unextracted plant material in the same carrier.

(Indenting and numbering added).

Both claim 10 and claim 13 recite the term “extract.” In claim 10, the term first appears in the phrase “[a]n extract of plant material from family Euphorbiae and species Croton.” Similarly, in claim 13, the term first appears in the phrase “[a]n extract of plant material from species Croton family Euphorbiae.” We consult the specification for assistance in defining this term. It is clear from the specification that the application deals with a solvent extraction process. (See, e.g., Specification 7:15). Accordingly, we will apply the definition found in The Penguin Dictionary of Chemistry, Second Edition, 1990, p. 170, which defines “extract” as follows:

In solvent extraction a portion of the feed is preferentially dissolved by the solvent and recovered by distilling off the solvent. This constitutes the extract.

From this definition, we arrive at a conclusion that the claim term “extract” means a solvent extracted portion of plant material from Croton.

Next, the claims require us to interpret the term “plant material.” We do so literally and broadly. This term, as presented, is inclusive of the entire plant, i.e. leaves, roots, bark, wood, sap, and latex. It also may include “Sangre de grado,” which the Appellant describes as the “viscous latex

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derived from various *Croton* species plants found primarily in the Amazon River basin.” (Specification 2:13). The term does not, however, exclude any portion of the plant.

We now come to the first ambiguity in claim 10. Paragraph (2) recites “the extract at a concentration of 1mg/mL of 50% (v/v) ethanol/water having reduced UV absorbency of about at least 4.3 between the range of 390 nm and 430 nm relative to the absorbency within the same range for unextracted plant material.” This paragraph is the principal subject of contention between the Examiner and the Appellant, and the only portion of the claim that is said to define it over the known and cited prior art. It is not in dispute that the Sangre de Grado, or Dragon’s Blood, was well-known to reduce nausea, emesis, retching, and itching.

The Examiner found that the “1mg/mL” phrase has “no patentable weight” because it is unclear what the amount of the Euphorbiae is relative to the claimed composition. (Final Rejection, Jul. 13, 2006, p. 5). The Appellant is of the viewpoint that the “1 mg/mL” description helps to characterize the reduced ultraviolet absorbance of the extract in the specified range. (Br. 12:18-23).

The Examiner is incorrect in finding that the “1 mg/mL” of claim 10 is not a limitation having weight. It appears to us that the Appellant is attempting to characterize the extract using a reference to a baseline material, which would be a limitation to the extract. It is critical to understand this limitation in order to understand how the claim would be defined over the prior art, if at all. *Amgen Inc. v. Chugai Pharm. Co. Ltd.*,

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927 F.2d 1200, 1218 (Fed. Cir. 1991) (noting the closeness of the prior art in doubting the meaning of the claims).

The specification provides some insight into how one of ordinary skill in the art would interpret and apply this limitation, but not enough to render the limitation clear and definite.

The specification describes that the first step of an extraction process involves mixing the “[l]atex, or sap from *Croton* species” with an organic solvent in a “1:1 proportion.” (Specification 7:20) Subsequently, the specification describes the relative absorbency of a “concentration of 1 mg of extracted latex to 1 mL of water.” (*Id.* 9:14).

Next, the specification describes the comparative absorbency of the proanthocyanidin between the “parent latex (SdG)” and the extract “(CGO 110).” (Specification p. 9, “[T]he reduced proanthocyanidin content is quantifiable spectrophotometrically. Relative absorbance of the extraction in the visible spectrum was compared to the absorbency peak of the parent latex (414 nm) in the visible range.”).

However, claim 10 does not tell one of ordinary skill in the art what the baseline is. It does not recite “latex.” Indeed, it recites “unextracted plant material” without any antecedent basis at all (e.g. “the” or “said”). Such plant material need not even be the same as the extracted plant material, by the literal language of the claims.

It would not have been apparent to one skilled in the art whether the unextracted plant material, as broadly claimed, is the latex or sap of *Croton*, or some other unextracted portion of the plant material, such as the leaf, branch, bark, etc. One of ordinary skill in the art could therefore not clearly

determine the baseline measurement. We will not import a limitation from the specification (plant material is the chosen language, presumably intentionally broader than “latex”). Without that baseline measurement, there is no way to know if the property of the extract is any different from the prior art.

Consequently, the Appellant’s attempt to characterize the test, and what it is compared against, is so flawed for at least this first reason as to make it impossible for one skilled in the art to determine the scope of claim 10.

Additionally, even if the “unextracted plant material” was understood to be the latex, neither the claim nor the specification describes the amount, concentration, or method of preparation of this “unextracted plant material” which is used in the comparison to the “1 mg/mL” of extract.

The second ambiguity in claim 10 relates to its recitation that the extract at a concentration of 1 mg/mL has a “reduced UV absorbency of about at least 4.3 between the range of 390 nm and 430 nm....” While the specification describes a “4.3 fold reduction in absorbance at 414 nm,” the claim does not define “4.3.”

This undefined result is particularly problematic because, in the art, absorbency does not technically have units, although absorbency is usually described with reference to “Absorbance Units” or “AU.” In any event, one skilled in the art may consider the recitation of “4.3”, without a description to the contrary, as an absorbency unit. Even if the 4.3 was understood as a 4.3 fold reduction in absorbance, as described in the specification, the claim would still be indefinite as it fails to provide sufficient baseline information

such that absorbency values for either of the compared materials could be meaningfully compared.

Claims 12 depends from claim 10 and is indefinite for the same reasons as the independent claim, except that claim 12 defines the absorbency. Claim 12 recites that the UV absorbency of the extract in claim 10 “is about 0.110 Abs Units relative to about 0.515 Abs Units for the unextracted plant material.” (Br. 18). However, as discussed regarding claim 10, the claim remains indefinite because it does not provide sufficient baseline information to allow a skilled artisan to meaningfully compare the claimed extract with the “unextracted plant material.”

Claims 23 and 24 also depend from claim 10 and are indefinite for the same reasons discussed for claim 10.

We now turn to independent claim 13, which suffers defects under the second paragraph of 35 U.S.C. § 112 analogous to those of claim 10. Claim 13 states that the extract “at a concentration of about 1mg/mL of carrier has a reduced UV absorbency in the range of 390 nm and 430 nm of at least 4.3 relative to the same concentration of unextracted plant material in the same carrier.” As discussed above, the Appellant is attempting to characterize the extract using a reference to a baseline material, which would be a limitation to the extract. As in claim 10, claim 13 does not inform a skilled artisan what the baseline is. It is unclear whether the broadly claimed “unextracted plant material” is the latex or sap of Croton or some other unextracted portion of the plant material, such as the leaf, branch, bark, etc. One of ordinary skill in the art is not sufficiently informed so as to clearly determine the baseline measurement, and hence the scope of the claim.

Moreover, as discussed with claim 10, even if the “unextracted plant material” was understood to be the latex, neither the claim nor the specification describes the amount, concentration, or method of preparation of this “unextracted plant material” which is used in the comparison to the “1 mg/mL” of extract.

Claims 15 depends from claim 13 and is indefinite for the same reasons as the independent claim, except that claim 15 defines the absorbency. Claim 15 recites that the UV absorbency of the extract in claim 13 “is about 0.010 Abs Units relative to about 0.030 Abs Units for the unextracted plant material.” (Br. 19). However, as discussed regarding claim 13, the claim remains indefinite because it does not provide sufficient baseline information to allow a skilled artisan to meaningfully compare the claimed extract with the “unextracted plant material.”

Claims 14, 19, and 20-22 also depend from claim 13 and are indefinite for the same reasons discussed for claim 13.

It is the applicant’s burden to precisely define the invention. *In re Morris*, 127 F.3d 1048, 1056 (Fed. Cir. 1997)(citing 35 U.S.C. § 112 ¶ 2, “The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”). As written, the Appellant’s independent claims 10 and 13 are indefinite, even in light of the specification. The scope of the claims are so unclear that we cannot interpret them to resolve the raised issues regarding the Examiner’s rejections under 35 U.S.C. §102 and §103.

CONCLUSION OF LAW

Accordingly, we reverse the Examiner's rejections and enter a new ground of rejection under 35 U.S.C. §112, second paragraph for independent claims 10 and 13, and their dependent claims.

DECISION

The Rejection of claims 10, 12, 13, 15, and 19-24 under 35 U.S.C. § 102(b) is REVERSED.

The Rejection of claims 10, 12, 13-15, 19-22, and 24 under 35 U.S.C. § 103(a) are REVERSED.

A new ground of rejection under 35 U.S.C. §112, second paragraph, is ENTERED for independent claims 10, 12-15, and, 19-24.

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

37 C.F.R. § 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. . . .

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REVERSED

NEW GROUND OF REJECTION (37 C.F.R. §41.50(b))

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