

The opinion in support of the decision being entered today is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte
ROBERT S. JACOBS, LAURA MYDLARZ,
and RUSSELL G. KERR

Appeal 2007-0539¹
Application 10/264,026
Technology Center 1600

DECIDED: July 17, 2007

Before TONI R. SCHEINER, ERIC GRIMES, and NANCY J. LINCK,
Administrative Patent Judges.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims directed to pseudopterosin compositions. The claims stand rejected as anticipated by the prior art. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

¹ Heard April 3, 2007.

BACKGROUND

Gorgonian corals, “a diverse group of marine animals . . . commonly known as sea feathers, sea whips and sea fans” (Spec. ¶ 3), harbor endosymbiotic algal populations, collectively called *Symbiodinium spp.*

Various compounds which exhibit anti-inflammatory and anti-proliferative activities, including pseudopterosins, seco-pseudopterosins, diterpene aglycones, and tricyclic diterpenes, have been isolated from gorgonian corals. Because isolating the compounds requires destroying the corals, and because “animal products are often undesirable for use in pharmaceutical[s] and cosmetics” (*id.* at ¶ 4), attempts have been made to synthesize biologically active pseudopterosins, but “[t]hese chemical and biosynthetic methods are expensive and often unsuccessful” (*id.*).

The present inventors, on the other hand, have demonstrated that *Symbiodinium spp.* symbionts are “involved in the synthesis of pseudopterosin compounds and can produce pseudopterosin compounds without the aid of the host [gorgonian corals]” (*id.* at ¶ 26, and ¶ 138), and that “pseudopterosin compounds may be produced by or isolated from *Symbiodin[i]um* symbionts” (*id.* at ¶ 26).

“[T]he present invention relates to pseudopterosin compounds and pseudopterosin compositions” (Spec. ¶ 10), free of animal impurities, or of non-animal origin. Claims 14, 20, 33, 36, and 42 are representative, and read as follows:

14. A pseudopterosin composition which comprises at least one pseudopterosin compound and is free of animal impurities obtained by isolating, purifying or preparing the compound from a *Symbiodinium spp.* symbiont.

20. The pseudopterosin composition of claim 14, and further comprising a cosmetically acceptable carrier.

33. An extract of non-animal origin comprising at least one pseudopterosin compound in a concentration that is higher than pseudopterosin concentrations in coral extracts.

36. The pseudopterosin composition of claim 14, wherein the *Symbiodinium spp.* symbiont belongs to phylotype B1.

42. The pseudopterosin composition of claim 14, wherein the pseudopterosin compound is selected from the group consisting of pseudopterosins, seco- pseudopterosins, diterpene aglycones, tricyclic diterpenes, and derivatives thereof.

As defined in the Specification, the term ““pseudopterosin compounds’ include[s] natural and synthetic pseudopterosins, seco-pseudopterosins, diterpene aglycones, and tricyclic diterpenes” (Spec. ¶ 27). “Derivatives of pseudopterosin compounds include compounds that have chemical structures and activities that are similar to those compounds produced by, synthesized in, or isolated from *Symbiodinium spp.* symbionts or hosts thereof” (*id.* at ¶ 28), and “may be synthesized by derivatizing the various naturally occurring pseudopterosins . . . which are isolated from *Symbiodinium* hosts” (*id.*).

According to the Specification, “[the] distribution of the various pseudopterosin compounds is likely the result of different environmental conditions of the areas in which the hosts and symbionts are located” (*id.* at ¶ 32), and “[t]he symbionts may be the same or different” (*id.*). “Thus, . . . different pseudopterosin compounds from a variety of symbionts . . . may be obtained according to the present invention” (*id.*). For example, “extracts of

purified *Symbiodin[i]um spp.* symbiont preparations showed endogenous levels of PsA, PsB, PsC, [and] PsD” (*id.* at ¶ 26).

Claims 14-16, 18-20, 32-34, and 36-48 are pending, and stand rejected as follows:²

- I. Claim 20 under 35 U.S.C. § 102(e) as anticipated by Mohammadi.³
- II. Claim 20 under 35 U.S.C. § 102(b) as anticipated by Jacobs I.⁴
- III. Claim 42 under 35 U.S.C. § 102(b) as anticipated by Ghisalberti.⁵
- IV. Claims 14-16, 18-20, and 37-48 under 35 U.S.C. § 102(b) as anticipated by Jacobs II.⁶
- V. Claims 33 and 34 under 35 U.S.C. § 102(b) as anticipated by Roussis.⁷

² The most recent Examiner’s Answer (mailed May 23, 2006) contains what appear to be, at least in part, new or reinstated rejections. Under 37 C.F.R. § 41.39(b)(1)(2)(2006), Appellants have two options in responding to a new ground of rejection in the Answer: (1) request that prosecution be reopened before the Examiner; or (2) request that the appeal be maintained by filing a reply brief. Accordingly, Appellants’ Reply Brief, filed July 24, 2006, “in response to the Examiner’s Answer mailed 23 May 2006” (Reply Br. 1), will be treated as a request to maintain the appeal.

³ U.S. Patent 6,217,913 B1 to Mohammadi, issued April 7, 2001.

⁴ U.S. Patent 4,745,104 to Jacobs et al., issued May 17, 1988.

⁵ E.L. Ghisalberti, *A Tricyclic Diterpene form Eremophila serrulata*, 31 Phytochemistry 2168 (1992).

⁶ International Application WO 89/01334 by Jacobs et al., published February 23, 1989.

- VI. Claims 36, 44, and 45 under 35 U.S.C. § 102(b) as anticipated by Look.⁸
- VII. Claim 32 under 35 U.S.C. § 102(b) as anticipated by Jacobs I and Jacobs II.

DISCUSSION

There is no dispute that the references relied on by the Examiner describe pseudopterosins with anti-inflammatory, anti-proliferative, and analgesic activity. For example, Jacobs II describes Pseudopterosin A, a tricarboxylic diterpene glycoside, and “certain natural and synthetic derivatives of Pseudopterosin A, along with their seco-analogs” (Jacobs II 2: 30-34). “The various naturally occurring pseudopterosin compounds are isolated from [a] ‘crude extract’ [of *Pseudopterogorgia*] by a series of sequential silica gel chromatographic techniques . . . [and] [t]he final purification of the natural products is accomplished by high-performance liquid chromatography” (*id.* at 7: 19-22 and 29-32). The purified pseudopterosins and synthetic derivatives are incorporated into “pharmaceutical compositions for use as anti-inflammatory agents, anti-proliferative agents and/or analgesic agents” (*id.* at 4: 25-30 and 15: 2 to 26: 11). The disclosure of Jacobs I is similar.

⁷ Vassilios Roussis et al., *New Antiinflammatory Pseudopterosins from the Marine Octocoral Pseudopterogorgia elisabethae*, 55 J. Org. Chem. 4916 (1990).

⁸ Sally A. Look and William Fenical, *The Seco-Pseudopterosins, New Anti-Inflammatory Diterpene-Glycosides from a Caribbean Gorgonian Octocoral of the Genus Pseudopterogorgia*, 43 Tetrahedron 3363 (1987).

Ghisalberti describes a tricyclic diterpene containing the 3-*epi*-pseudopterosin skeleton, isolated from an extract of the terrestrial plant *Eremophila serrulata*. The 3-*epi*-pseudopterosin skeleton is also found in sponges, and “[m]ore examples have [] been found in the pseudopterosins, a class of anti-inflammatory and analgesic diterpene glycosides, produced by the marine octocoral *Pseudopterogorgia elisabethae*” (Ghisalberti 2169). According to Ghisalberti, the tricyclic diterpene from *E. serrulata* is “a 3-epimer of the aglycone derived from the pseudopterosins isolated from the Bahamas collection of *P. elisabethae*” (*id.*).

Roussis describes anti-inflammatory pseudopterosins A-L, at least one of which was pure enough to crystallize, isolated from extracts of *P. elisabethae* (Roussis 4918, left-hand col.).

Look describes seco-pseudopterosins with anti-inflammatory and analgesic activities, isolated from a Caribbean sea whip of the genus *Pseudopterogorgia* (Look 3363). “Specimens of *Pseudopterogorgia* . . . were extracted with chloroform and ethyl acetate. The combined extracts were chromatographed over TLC grade silica gel and fractions containing polar compounds were further fractionated by silica HPLC. Purification yielded the seco-pseudopterosins A-D (1-4) as the major components of the extract” (*id.* at 3365).

Mohammadi describes cosmetic compositions containing gorgonian extract in a crosslinked silicone elastomer base (Mohammadi col. 1, l. 58 to col. 2, l. 6).

The Examiner’s position is that “[t]he pseudopterosin compositions of the instant claims are not . . . patentably distinct from those of the prior art”

(Answer 7), “[e]ven though the prior art does not specifically teach pseudopterosins obtained from *Symbiodinium spp.* or other sources of non-animal origin” (*id.*).

Appellants argue essentially that the “claimed compositions are novel over the prior art in that they do not contain animal impurities . . . as the compositions and the ingredients/compounds in the compositions are obtained from non-animal sources and therefore it is impossible for trace amounts of animal impurities to be present” (Br. 5). The underlying implication here is that all the prior art compositions must contain animal impurities, since, according to Appellants, “the only way to ensure a pseudopterosin composition that is completely free of animal impurities is to obtain the pseudopterosin compounds from non-animal sources” (*id.* at 7-8).

It is well settled that “[t]he patentability of a product does not depend on its method of production.” *In re Thorpe*, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). Thus, the present claims merely require compositions containing the same pseudopterosin compounds *obtainable* from *Symbiodinium spp.*, wherein the compositions are free of animal impurities. “If the product in a product-by-process claim is the same as . . . a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *Id.*

“[I]n an *ex parte* proceeding to obtain a patent, . . . the Patent Office has the initial burden of coming forward with some sort of evidence tending to disprove novelty.” *See In re Wilder*, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970). Nevertheless, “when 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.” *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Likewise, “[w]here a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.” *In re Marosi*, 710 F.2d 799, 803, 218 USPQ 289, 292-93 (Fed. Cir. 1983). Shifting the burden under these circumstances is reasonable because of “the PTO’s inability to manufacture products or to obtain and compare prior art products.” *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

The issue raised by this appeal, then, is whether the Examiner has provided a reasonable basis for shifting the burden to Appellants to establish that the prior art pseudopterosin compositions do not contain pseudopterosin compounds obtainable from *Symbiodinium spp.*, and/or that the prior art compositions contain animal impurities.

We find that the references cited by the examiner describe pseudopterosin compositions containing pseudopterosin compounds, and synthetic derivatives thereof, of the same classes obtained from *Symbiodinium spp.* Moreover, because the pseudopterosin compounds were isolated and purified before being incorporated into compositions, we find that the Examiner has established a reasonable basis for concluding that the prior art compositions are free of animal impurities. Therefore, we find that the Examiner has provided a reasonable basis for shifting the burden to

Appellants to establish that the prior art pseudopterosin compositions do not contain pseudopterosin compounds obtainable from *Symbiodinium spp.*, or that the prior art compositions contain animal impurities.

Appellants point to Figures 1 and 2 of the Specification, thin layer chromatograms which show “the separations for the algal fraction (*Symbiodinium spp.* symbiont) and the coral (animal) fraction[,]” as evidence that the two fractions “are clearly different” (Br. 2-3). We do not disagree, but Appellants have not explained how the fact that crude coral and algal extracts are different has any bearing on whether the pseudopterosin compositions of the cited prior art contain animal impurities. Therefore, this evidence does not persuade us that the claimed compositions are not anticipated by the prior art compositions.

Appellants additionally rely on two “HPLC chromatographs of an extract from *Symbiodinium spp.* (algae) (Figure A) and an extract of *Pseudopterogorgia elisabethae* (coral) (Figure B)”⁹ (Br. 6), as evidence that “the algae composition/extract contains different compounds as well as having different concentrations of the pseudopterosin compounds when compared to the coral composition/extract as evidenced by the difference in the peaks” (*id.* at 7). Appellants argue that “the algae extract clearly has many other compounds as indicated by the numerous peaks not observed from the coral extract. Since the algae extract is from a non-animal origin, these additional compounds in the algae extract are not animal impurities,

⁹ These two chromatographs were originally submitted with Appellants’ Amendment-After-Final on June 17, 2004, and are reproduced on pages 6 and 7 of the Brief.

such as animal proteins, animal lipids and other animal compounds” (*id.*). That is beside the point. Appellants have not provided an expert analysis of the peaks on these chromatographs, nor have Appellants identified anything in the coral fraction that is not also in the algal fraction. Thus, Appellants have not established that there are any “animal impurities” in the coral fraction. In any case, even if animal impurities were apparent in the coral fraction, it would have no bearing on whether the prior art pseudopterosin compositions contain animal impurities. Again, this evidence does not persuade us that the prior art compositions do not anticipate the claimed compositions.

In this regard, Appellants also argue that “the claimed extracts . . . are not the same as an ‘HPLC extract’” and “[t]he claimed extracts, algal extracts comprise other components/ingredients/impurities from the algae The algal extracts may be subjected to HPLC methodologies to provide a highly pure solution of a given compound, *i.e.* an HPLC extract . . . [but] the resulting so called ‘HPLC extract’ is not the same as the original algal or coral extract” (Br. 9). This argument is not persuasive. As discussed above, most of the claims merely require compositions, free of animal impurities, comprising at least one pseudopterosin obtainable from *Symbiodinium spp.* Even those claims directed to an “extract” (claims 33, 34, and 48) fail to distinguish between an “‘HPLC extract’ . . . [and] the original algal or coral extract” (*id.*).

Finally, Appellants argue that “[o]ne cannot possibly hold that ALL the peaks in the coral HPLC are not animal impurities” (Br. 7), and “the only way to ensure a pseudopterosin composition that is completely free of

animal impurities is to obtain the pseudopterosin compounds from non-animal sources" (*id.* at 7-8). Nevertheless, attorney argument is not evidence. *In re Pearson*, 494 F.2d 1399, 1405, 181 USPQ 641, 646 (CCPA 1974). Nor can it take the place of evidence lacking in the record. *Meitzner v. Mindick*, 549 F.2d 775, 782, 193 USPQ 17, 22 (CCPA 1977).

We find that the Examiner has established a sound basis for believing that the prior art compositions meet all the limitations of the present claims, properly shifting the burden to Appellants to show otherwise. We further find that Appellants have not adequately discharged their burden of rebuttal, by argument or evidence.

SUMMARY

Rejections I-VII of claims 14-16, 18-20, 32-34, and 36-48 under 35 U.S.C. § 102(b) are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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