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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JEAN KRUTMANN

Appeal 2019-000294
Application 13/038,641
Technology Center 1600

Before RICHARD M. LEBOVITZ, JOHN G. NEW,
RACHEL H. TOWNSEND *Administrative Patent Judges.*

LEBOVITZ, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 11 and 13. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as Bitop Atkiengesellschaft für Biotechnische Optimierung. Br. 3.

Claims 11 and 13 stand finally rejected by the Examiner under 35 U.S.C. § 112(a) (2012) or 35 U.S.C. § 112 (2006), first paragraph, as failing to comply with the enablement requirement. Final Act. 2.

Claim 11, the only independent claim on appeal, is reproduced below:

> 11. A method for counteracting lung tissue exposure to suspended particulate in a patient in need thereof, comprising administering by inhalation an effective amount of at least one osmolyte selected from ectoine, hydroxyectoine or a pharmacologically compatible salt thereof to the patient.

REJECTION

The Examiner determined that claims 11 and 13 do not comply with enablement requirement of 35 U.S.C. §112, first paragraph, and 35 U.S.C. § 112(a). The Examiner found that the claimed method "for counteracting lung tissue exposure to suspended particulate in a patient" encompasses "lung ailments from foreign body inhalation such as asbestosis and silicosis, cystic fibrosis, or even cancer such as mesothelioma, squamous, small cell lung cancer." Ans. 4. The Examiner found that it could not be predicted at the time of the invention whether the recited osmolytes would treat the broad conditions and diseases encompassed by the claims, but not disclosed in the Specification. Ans. 7.

CLAIM INTERPRETATION

We begin with claim interpretation because before we can consider the enablement rejection, we must determine the breadth of the claims.

During patent examination proceedings, claim terms are given "the broadest reasonable meaning . . . in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever

enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Claim 11 is a method "for counteracting lung tissue exposure to suspended particulate in a patient." The Specification explains that "harmful effects" are "associated with airborne particles" present in air pollution "due to an interaction between these molecules and the human pulmonary tissue." Spec. 1. "As a result," the Specification discloses "inflammatory and, at times, even malignant pulmonary diseases will be experienced. Suspended particulate matter entering the lungs is thus to be viewed as one of the most significant causes of pulmonary diseases." *Id.*

The Specification further discloses that it "has been found that pharmaceutical preparations in inhalable form containing one or several osmolytes, the salts thereof and/or their equally effective derivatives, surprisingly, enable an effective prophylaxis to be achieved against the above described diseases as well as treatment of such diseases" associated with airborne particulate. Spec. 2. The Specification teaches that osmolytes, which include the claimed ectoine and hydroxyectoine, are "low-molecular organic substances present in the intracellular environment" of extremophilic bacteria which are involved in the "high temperature stability of cell structures" of such bacteria. Spec. 2–3.

The Specification teaches that osmolytes have been used to treat skin diseases and it "has been assumed in that context that these agents are conducive to the stabilization of enzymes and other biomolecules. Spec. 3. However, the Specification discloses [u]ntil now, it has not been found in which way osmolytes act on tissue other than that of the skin." Spec. 3–4.

The Specification teaches that external application of hydroxyectoine to the cornea and iris of rabbits had caused irritation and sensitization. Spec. 4.

The Specification further discloses:

> Surprisingly, it has now been determined that osmolytes are not only well tolerated by human bronchial and lung tissue including pulmonary alveoli but, unexpectedly, have an excellent prophylactic effect *counteracting the noxious influence* of suspended particulate irrespective of the nature of such airborne particles. They are also suitable for the treatment of diseases causally originating through such effects.

Spec. 4 (emphasis added).

While the Specification and claims use the term "counteracting," there is no definition of this term, no description of the kind of activity embraced by the term, nor any other explanation by which to glean the meaning of the term. Nor is there any discussion in the Specification as to what is embraced by ectoine and hydroxyectoine counteracting the "noxious influence" of the suspended particulates in lung tissue, which tissue is the target of these osmolytes in rejected claim 11. Because of the lack of information as to what is meant by "counteracting" in the Specification, we consult a general purpose dictionary for assistance in construing the term. Given the dictionary definition and the vague manner in which the term is used in the Specification, we understand "counteracting" to mean having a restraining or neutralizing effect.[2]

The Examiner interpreted "counteracting lung tissue exposure to suspended particulate" to include disease prophylaxis and treatment.

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[2] Counteract: "to make ineffective or restrain or neutralize the usually ill effects of by means of an opposite force, action, or influence." https://www.merriam-webster.com/dictionary/counteract (last accessed Oct. 30, 2019).

Appellant states that "the treatment of disease and the counteracting behavior of osmolytes are distinct actions." Br. 5. To support this position, Appellant points to the same disclosure on page 4 of the Specification reproduced above. *Id.*

We disagree that the cited passage on page 4 of the Specification establishes that the osmolyte "counteracting" action is distinct from the treatment of disease using osmolytes. Rather, the passage can reasonably be interpreted as indicating that the osmolytes unexpectedly had excellent disease treatment capability by counteracting the noxious influence as well as being suitable for such disease treatment.

The passage first states "that osmolytes . . . have an excellent prophylactic effect counteracting the noxious influence of suspended particulate. Spec. 4. Therefore, the "counteracting" action of the osmolytes results in the prophylactic effect, i.e., disease prevention. The next sentence referred to by Appellant states the osmolytes "are also suitable for the treatment of diseases causally originating through such effects." Spec. 4. We understand the reference to "such effects" to mean "the noxious influence of suspended particulate." The sentence therefore states the fact that osmolytes can be used to treat disease caused by the suspended particulate. It does not require the disease treatment to be distinct from the counteracting effect of the osmolytes.

Appellant has not provided an adequate explanation as to why disease treatment is excluded from the scope of "counteracting lung tissue exposure to suspended particulate." (Appeal Br. 10). Appellant's argument appears to be that once the particulates have entered the lungs and exerted their

"harmful effects" (Spec. 1), the mechanism of treatment by the osmolyte is different from "counteracting" their deleterious diseasing causing effect.

The only passage cited by Appellant to support this argument is on page 4 of the Specification, and as discussed above, the cited passage does not exclude the recited "counteracting" action from being responsible for the disease treatment.

The Specification also does not describe the mechanism through which the osmolytes 1) counteract the deleterious effects of the suspended particulate, 2) prevent disease, or 3) treat disease that would elucidate whether the counteracting property is distinct from the disease treatment property. The Specification describes osmolytes previously known effects on cell structure stability (Spec. 2), on the stabilization of enzymes and other biomolecules (Spec. 3), and as having antioxidant protective effects (Spec. 3). The Specification did not attribute the osmolytes beneficial effects on the lung to any of the known osmolyte properties.

On the other hand, we find that the claim language when read in light of the Specification is reasonably interpreted to include disease treatment. Claim 11 recites "counteracting lung tissue exposure to suspended particulate." When a disease is *treated* by the recited osmolyte, the noxious effects of the particulate are counteracted because their disease-causing effects are neutralized (dictionary definition of "counteract"). The result of administering the osmolyte is to treat the disease and therefore the noxious influence of suspended particulate is counteracted, even if the treatment occurs after the particulate has caused the disease and the treatment treats a secondary result (e.g., tissue injury) of the particulate activity.

Prophylaxis or disease prevention is clearly linked to the counteracting effect of the particulate on page 4 of the Specification ("it has now been determined that osmolytes are not only well tolerated by human bronchial and lung tissue including pulmonary alveoli but, unexpectedly, have an excellent prophylactic effect counteracting the noxious influence of suspended particulate") and therefore falls squarely within the scope of claim 11.

For the foregoing reasons, we find that the claimed method "for counteracting lung tissue exposure to suspended particulate in a patient in need thereof" includes both the prophylaxis and treatment of lung disease, as well as other countering effects.

DISCUSSION

"[T]o be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir.1993) (citing *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991)); *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988); *In re Fisher*, 57 C.C.P.A. 1099, 427 F.2d 833, 839 (1970). In determining whether "undue" experimentation is required to make and use a claimed invention, courts may consider the following factors:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Wands, 858 F.2d at 737 (Fed. Cir. 1988).

As explained above, the breadth of the claims is broad (Wands factor 8), including prevention and treatment of lung conditions caused or exacerbated by suspended particulates, such as inflammatory disease, malignant pulmonary disease (Spec. 1), silicosis, and mesothelioma (Final Act. 3), as well as any amount of neutralizing activity of the osmolyte on the particulate in the lung. The analysis below mentions disease treatment. However, even if treatment were excluded, the same rationale applies to disease prevention and other neutralizing effects of the osmolyte.

Despite the breadth of the claims, the only examples (Wands factor 3) disclosed in the Specification are Examples 1 and 2 of making gas and powder inhalants comprising ectoine and hydroxyectoine. Spec. 7. There is no example in which either osmolyte, alone or both combined as in the inhalants of Examples 1 and 2, are used to counteract a particulate in the lung, let alone prevent or treat a condition caused by the particulate.

The Specification discloses a broad range of active agents that can be present in a formulation: "between 0.005 and 20 percent by weight [a 4,000-fold difference in range] based on the weight of the carrier material employed. Preferred is a range between 0.05 and 2 percent by weight [a forty-fold difference in range]." Spec. 7. However, the Specification does not disclose what amount is "an effective amount" to counteract "lung tissue exposure to suspended particulate" as recited in claim 11. For example, the Specification does not disclose an effective dosage or frequency of administration necessary to achieve the claimed purpose. The Specification also does not provide guidance on how to determine an "effective amount" and whether such amounts would be the same for all the conditions encompassed by the claims, such as treating or preventing inflammatory

lung disease or malignant pulmonary disease (Spec. 1, ¶¶ 1, 2). Therefore, there is a paucity of guidance of how to use the claimed osmolytes to counteract a suspended particulate in the lung (Wands factor 2).

Appellant contends there is sufficient direction in the Specification (Br. 7), but did not explain how one of ordinary skill in the art would know how much osmolyte to administer to counteract lung tissue exposure to suspended particulate, and how much would prevent diseases caused by their harmful effects.

Appellant also argues that guidance is provided because "the topical application of the osmolytes ectoine and hydroxyectoine for treating skin and eyes has been described." Br. 6. However, the Specification does not disclose that the skin treatment with osmolytes operates in the same way as the claimed ectoine and hydroxyectoine in counteracting particulates. Moreover, Appellant did not explain how applying the osmolyte externally to the skin provides guidance on administering the osmolytes internally to the lung.

Furthermore, the Specification states:

> the external application of hydroxyectoine on the cornea and iris of the eyes of rabbits . . . caused initial irritation and sensitization of the conjunctiva (redness, chemosis and discharge) which, however, disappeared afterwards but, nevertheless, were clear indications to those skilled in the art that incompatibility was to be expected in the case of more sensitive tissue surfaces.

Spec 4.

As a result of adverse effects on the skin, the inventors found it surprising that osmolytes were tolerated by bronchial and lung tissue and had a prophylactic effect. Spec. 4. Thus, it is not evident from the

Specification how the disclosure on eye and corneal treatment, which were found to cause irritation when applied externally, would provide guidance on internally administering the osmolytes to the lung. For this reason, we also find direction in the Specification on how to use the claimed osmolytes to counteract a suspended particulate in the lung to be deficient (Wands factor 2).

We also must consider the level of skill in the art when making an enablement determination (Wands factor 6). A person of skill in the relevant art would be a physician or other health care provider knowledgeable in disease treatment or prevention. However, these specialized skills do not make up for the deficiencies in the Specification because no guidance is provided as to the effective dosage to counteract the particulates noxious influence in the lung or what conditions would be counteracted by the osmolyte. Without such information, the health care provider would not know what condition can be prevented or treated with the claimed osmolyte, and if the provider did know, what would be the appropriate dosage to achieve success.

Appellant contends the level of skill in the art is "high" (Wands factor 6) and that "studies on the effects of suspended particulates on lung tissue have been carried out by scientists." Br. 7. Appellant, however, did not explain how this high level of skill and the lung studies would enable one of ordinary skill in the art to carry out the full scope of the claim, such as to determine the dosages and frequency of administration to prevent inflammation and malignant pulmonary disease. Appellant points to the disclosure on pages 1 and 2 of the Specification as to how the lung responds to suspended particulates (Br. 7), but Appellant does not explain how this

knowledge enables the skilled worker to counteract the suspended particulate with the claimed osmolytes and prevent or treat disease as a result.

With respect to unpredictability (Wands factor 7), the Examiner provided evidence of the unpredictability of treating cancer, one of the indications encompassed by the claims. Final Act. 5–7. Certainly, if the mechanism of "counteracting' is not described in the Specification, and it has not been explained whether the osmolyte interacts directly with the particulate, or by acting directly on the lung or other internal tissues, and in view of the lack of guidance in the Specification (no working examples, no effective amounts, no meaningful discussion of what "counteracting" includes), it would be unpredictable whether the recited ectoine and hydroxyectoine action in countering suspended particulate would prevent or treat the plethora of conditions, including cancer, and activities encompassed by the claims.

As explained above, the claim scope is broad, including prophylaxis, treatment, and other neutralizing effects on particulates using the recited osmolytes, with no guidance on the mechanism of action or how to determine whether the "noxious influence" of the suspended particulate is counteracted by ectoine or hydroxyectoine. Moreover, while the "nature of the invention" (factor (4) of Wands factors) is broad and unpredictable, there is a lack of guidance in how to use the recited osmolytes to counteract the noxious influence of suspended particulate.

For the foregoing reasons, the enablement rejection of claim 11 and dependent claim 13 is affirmed.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
11, 13	112	Enablement	11, 13	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED