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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BRUCE W. HUDSON,
GARY W. OPPERMAN, and ADRIAN T. RAICHE

Appeal 2017-010176
Application 13/334,154
Technology Center 1600

Before RICHARD M. LEBOVITZ, JEFFREY N. FREDMAN, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal^{1,2} under 35 U.S.C. § 134 involving claims to a method of preparing an emulsion. The Examiner rejected the claims as being of improper dependent form and as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

¹ Appellants identify the Real Party in Interest as Evonik Corporation (*see* App. Br. 1).

² We have considered and herein refer to the Specification of Dec. 22, 2011 (“Spec.”); Final Office Action of Aug. 24, 2016 (“Final Act.”); Appeal Brief of Feb. 23, 2017 (“App. Br.”); and Examiner’s Answer of May 9, 2017 (“Ans.”).

Statement of the Case

Background

“Encapsulation of pharmaceuticals in biocompatible, biodegradable polymer microparticles can prolong the maintenance of therapeutic drug levels” (Spec. ¶ 3). “Several techniques for the production of microparticles containing biological or chemical agents by an emulsion-based manufacturing technique have been reported” (*id.* ¶ 5). The Specification teaches a need for “a column that is configured to maintain a consistent path length and to prevent formation of preferred channels in a packed bed during scale-up of an emulsion process” (*id.* ¶ 9).

The Specification teaches “the column includes at least one divider positioned within the interior cavity. . . . the dividers are configured to partition the packing material and to direct fluid flow through the column” (Spec. ¶ 10).

The Claims

Claims 16–20, 22–24, 27, and 30 are on appeal. Independent claim 16 is representative and reads as follows:

16. A method of preparing an emulsion, the method comprising:

positioning a packing material within a column, the column having a longitudinal axis and a periphery defining an interior cavity, the interior cavity having a longitudinal length; the packing material configured to permit fluid flow through the column along the longitudinal axis, the column comprising:

an inlet in fluid communication with the interior cavity;

an outlet in fluid communication with the interior cavity;

and

at least one divider positioned within the interior cavity, each divider of the at least one divider extending along at least a portion of the longitudinal length of the interior cavity,

wherein the at least one divider is configured to partition the packing material and direct fluid flow therethrough the interior cavity;

introducing a plurality of fluids through the inlet of the column under laminar flow conditions, wherein the plurality of fluids combine within the interior cavity of the column to form an emulsion product; and

collecting the emulsion product through the outlet of the column;

wherein the method is insensitive to flow rates; and

wherein the column can be utilized at any pressure.

The Issues

- A. The Examiner rejected claim 22 under 35 U.S.C. § 112, fourth paragraph as being of improper dependent form (Final Act. 2–3).
- B. The Examiner rejected claims 16–20, 22–24, 27, and 30 under 35 U.S.C. § 103(a) as obvious over Zeigerson³ (Final Act. 3–7).

A. 35 U.S.C. § 112, fourth paragraph

Dependent claim 19 limits independent claim 16 by reciting a first phase that comprises a solvent and “an active agent.” The Examiner finds that Markush group of active agents recited in claim 22 does not further limit the generic active agent recited in claim 19 (*see* Final Act. 2). Specifically, the Examiner finds “Claim 22, which depends from claim 19, recites a

³ Zeigerson, US 2007/0190154 A1, published Aug. 16, 2007.

Markush group of active agents which is so infinitely broad and generic as to encompass the entire spectrum of any and all active agents possibly covered in claim 19” (Final Act. 2). The Examiner finds that “claim 22 provides that the group of active agents can include any ‘organic molecule’ and also any ‘inorganic molecule’, as well as any ‘salt’ (i.e. organic or inorganic salt) which alone would thus cover the entire spectrum of active agents known to man” (*id.*).

Appellants contend

Claim 22, on the other hand, is directed to the method of claim 19, wherein the active agent of the first phase is specifically recited. Therefore, claim 22 does further limit the active agent of claim 19. While claim 22 may cover a sub-generic group of active agents recited in claim 19, the meets and bounds of the sub-genus are apparent to one skilled in the art and as such, the claim is not in violation of any requirement of 35 U.S.C. § 112.

(App. Br. 9).

We agree with the Examiner because, as the Examiner points out, every molecule is either a salt, an “organic” or an “inorganic” molecule. That is, the term “organic” is defined as “[o]f or relating to any covalently bonded compound containing carbon atoms”.⁴ Meanwhile, “inorganic” is defined as “[n]ot an organic substance; not a hydrocarbon or a derivative of hydrocarbon.”⁵ Therefore, as the Examiner points out, these two words

⁴ See Organic. (1992). In C. G. Morris (Ed.), Academic Press Dictionary of Science and Technology (4th ed.). Oxford, UK: Elsevier Science & Technology. Retrieved from <https://search.credoreference.com/content/entry/apdst/organic/0?institutionId=743>

⁵ See Inorganic. (1992). In C. G. Morris (Ed.), Academic Press Dictionary of Science and Technology (4th ed.). Oxford, UK: Elsevier Science & Technology. Retrieved from <https://search.credoreference.com/content/>

along with the term “salts” reasonably encompass every active agent because every chemical either contains carbon or lacks carbon or is a salt. For this reason, claim 22 does not further limit claim 19 because it does not require a set of active agents that differs from that of claim 19. We, therefore, affirm this rejection.

B. 35 U.S.C. § 103(a) over Zeigerson

The Examiner finds “Zeigerson discloses a method of preparing an emulsion” that includes using a packing material in a column with an inlet and outlet, introducing “fluids through the inlet of the column under laminar flow conditions,” collecting an emulsion product, where the method is insensitive to flow rates and can be used at any pressure (Final Act. 4–5).

The Examiner acknowledges that Zeigerson “does not explicitly disclose that the additional material inserted at either end is a divider that extends along at least a portion of the longitudinal length of the interior cavity and is configured to partition the packing material” (Final Act 5).

The Examiner finds it obvious

to insert a separate material into the inlet end of the tube, the separate material being a “divider” that extends along at least a portion of the longitudinal length of the interior cavity and is configured to partition the packing material, with the reasonable expectation that the resulting tube will successfully permit the separate phases to be introduced individually, albeit simultaneously, into the packed column through different tubes, and that the two phases merge inside the column (i.e. further interior from the entrance of the tube) to form the desired emulsion product.

(Final Act. 6).

Appellants contend “Zeigerson’s disclosure that separate phases can be introduced individually into the packed column does not render obvious the use of dividers to partition the packing material because the two phases nevertheless subsequently merge inside the column and travel through column without any dividers” (App. Br. 4). Appellants point out “there is no teaching anywhere in the general knowledge of the art that teaches such a divider material” (*id.* at 5).

Appellants contend a “skilled artisan would not contemplate that the enclosure of Zeigerson could indicate both an enclosure cap and a partition or divider that would further partition or divide the interior cavity of the column” (App. Br. 6). Appellants contend

One of ordinary skill in the art would not obviously recognize that the best way to keep the two distinct phases flowing on divided pathways within the packed column until the proper merge point is to insert a divider. A divider was not taught or suggested by the cited prior art, and it was only with the benefit of improper hindsight reasoning after reading Appellants’ own disclosure that a rejection was formulated.

(App.Br. 7).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that Zeigerson renders obvious the use of a “divider positioned within the interior cavity” of a column for emulsion preparation as required by claim 16?

Findings of Fact

1. The Specification teaches “the column 10 can further comprise an inlet screen attached to the inlet of the column and an outlet screen attached to the outlet of the column, and the at least one divider can be

secured thereto at least one of the inlet screen and the outlet screen” (Spec. ¶ 45).

2. Zeigerson teaches “a process for preparing an emulsion that produces microparticles containing biological or chemical agent” (Zeigerson ¶ 17).

3. Zeigerson teaches “a packed bed apparatus for the production of microparticles through an emulsion-based technique. . . . [that] may further provide a material capable of insertion into both ends for enclosure of materials in such apparatus” (Zeigerson ¶ 41).

4. Zeigerson teaches the process “is insensitive to flow rates within the laminar flow region” and “may be utilized at any pressure compatible with the equipment utilized” (Zeigerson ¶¶ 45, 51).

5. Zeigerson teaches

Microparticle size distribution may be manipulated by altering the packing material size, shape and type; rearranging the inlet or outlet enclosures; alteration of the physical properties of the first, second or third phases; altering the length or width of the vessel and the like. For example, the final microparticle size can be determined by the size of the packing material, such as the diameter of a glass bead. Additionally, the length of the vessel may directly affect the particle size distribution.

(Zeigerson ¶ 47).

6. Zeigerson teaches a “feed vessel may be utilized in the present invention to hold the first or second phases” and that a “tube may run from each [feed vessel] through a pump and later merge with the tube from the other one to the entrance to the packed bed apparatus. The merge may also happen . . . inside the packed bed apparatus itself” (Zeigerson ¶ 57).

7. Figure 2A of the Specification is reproduced below:

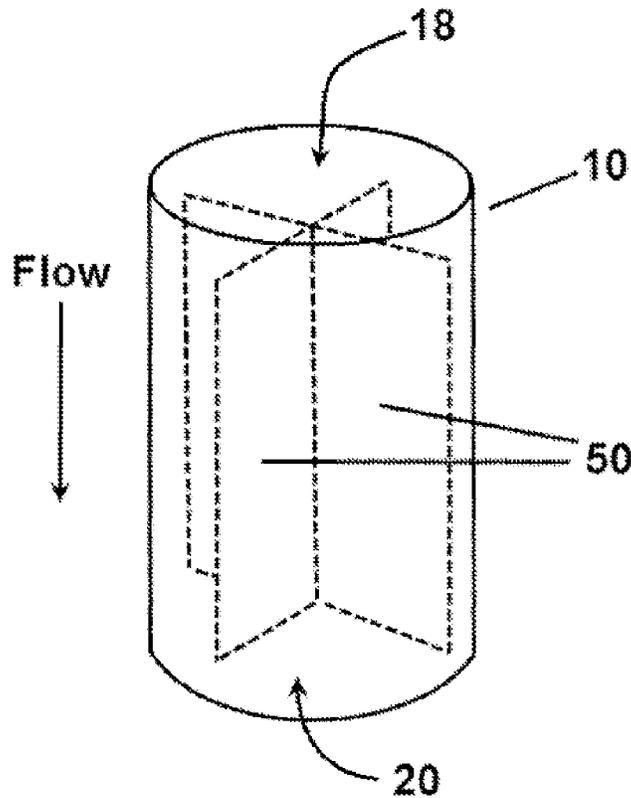


FIG. 2A

“Figure 2A is a perspective view of an exemplary column having dividers”
(Spec. ¶ 14).

Principles of Law

The Examiner has the initial burden of establishing a prima facie case of obviousness under 35 U.S.C. § 103. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

A prima facie case for obviousness “requires a suggestion of all limitations in a claim,” *CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) and “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the

claimed new invention does.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

Analysis

We have interpreted a “divider” to mean a physical structure that partitions a least a portion of a column, *e.g.*, *see* Fig. 2A (FF 7). This is consonant with both the Specification and with the ordinary meaning of the term “divider” as “something serving as a partition between separate spaces or areas.”⁶

We therefore agree with Appellants that a “divider was not taught or suggested by the cited prior art, and it was only with the benefit of improper hindsight reasoning after reading Appellants’ own disclosure that a rejection was formulated” (App. Br. 7).

The Examiner does not provide evidence that dividers were expressly taught by Zeigerson, and we note the Examiner expressly acknowledges that “Zeigerson does not explicitly disclose that the additional material inserted at either end is a divider” (Ans. 5).

Also, the Examiner does not provide evidence that dividers were inherently taught by Zeigerson. In particular, the Examiner does not establish that the inlets of Zeigerson extended into the interior cavity. That is, while Zeigerson may well suggest the use of two separate inlets that merge “inside the packed bed apparatus” (FF 6), Zeigerson does not demonstrate that this merger results in a divider because the merger may reasonably occur in a single tube prior to entry into the packed bed inside the apparatus. “Inherency . . . may not be established by probabilities or

⁶ *See, e.g.*, <https://www.merriam-webster.com/dictionary/divider>.

possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.” *MEHL/Biophile Int’l. Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999).

Lastly, the Examiner does not provide a persuasive reason for the inlets of Zeigerson to extend into the packing bed and serve to partition at least a portion of the column, nor does the Examiner provide a persuasive reason to include dividers based on the express disclosure of Zeigerson. Nor has the Examiner provided any other reason from Zeigerson that would suggest that an implicit motivation to combine exists because “the ‘improvement’ is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). In contrast, Appellant has provided reasons why dividers would not have been included based on Zeigerson, including the argument that “one skilled in the art would not be motivated to include such a divider when Zeigerson already demonstrates superior results. Zeigerson teaches the production of emulsion-based microparticles that provides narrow, reproducible, particle size distribution” (App. Br. 6).

Conclusion of Law

The evidence of record does not support the Examiner’s conclusion that Zeigerson renders obvious the use of a “divider positioned within the interior cavity” of a column for emulsion preparation as required by claim 16.

SUMMARY

In summary, we affirm the rejection of claim 22 under 35 U.S.C. § 112, fourth paragraph as being of improper dependent form.

We reverse the rejection of claims 16–20, 22–24, 27, and 30 under 35 U.S.C. § 103(a) as obvious over Zeigerson.

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-IN-PART