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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JULIEN P. FEY, KELLY M. S. BLATT, DAVID C. BURNS, and ANTHONY R. EISENHUT

Appeal 2020-001597
Application 15/332,572
Technology Center 1600

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant[1] seeks our review,[2] under 35 U.S.C. § 134(a), of the Examiner's decision to reject claims 1, 6, 21, and 22. (Appeal Br. 3.) 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. Appellant identifies the Real Party in Interest as NOVASTERILIS, INC. (*See* Appeal Br. 1.)

[2] We consider the Specification dated August 2, 2018 ("Spec."), Final Office Action issued February 25, 2019 ("Final Act."), the Appeal Brief filed August 29, 2019 ("Appeal Br."), the Examiner's Answer issued October 28, 2019 ("Ans."), and the Reply Brief filed December 27, 2019 ("Reply Br.").

INTRODUCTION

Appellant's Specification provides a method for producing biological vehicles impregnated with cargo molecules. (Spec. 2.) The Specification defines the term "impregnating" as "physical penetration of the biological vehicle(s) by the cargo molecule(s)." (*Id.* at 12.) The biological vehicles may include bacterial and fungal spores, cells, vesicles, or viruses. (*Id.* at 13.) The cargo molecules may include drugs, imaging reagents, ions, natural compounds, and synthetic compounds. (*Id.*)

The Specification explains that applying subcritical and supercritical fluids provides solvation and penetration to effectively impregnate biological vehicles with cargo molecules. (*Id.* at 12–13.) The Specification describes the preferred treatment fluid as supercritical carbon dioxide at a temperature exceeding 31.1° C and a pressure exceeding 1071 psi, or subcritical carbon dioxide at a temperature of 25–35° C and a pressure of 750–1070 psi. (*Id.* at 13–14.)

Appellant's claim 1 recites:

> A method for impregnating a biological vehicle with a cargo molecule, comprising:
>
> mixing the biological vehicle and the cargo molecule in a suspension to create a cargo molecule and biological vehicle mixture, the biological vehicle is a spore, cell, virus, or cell-derived vesicle and the cargo molecule consists essentially of a drug, a prodrug, an imaging reagent, an ion, a natural compound, a synthetic compound, a polypeptide, a small peptide, a protein, an enzyme, an antigen, an antibody, a carbohydrate, a nucleic acid, DNA, RNA, or PNA;

placing the cargo molecule and biological vehicle mixture inside a pressure vessel;

subjecting the cargo molecule and biological vehicle mixture to subcritical or supercritical fluid to affect the surface of the biological vehicle allowing the cargo molecule to bind to and penetrate the biological vehicle;

returning pressure and temperature within the pressure vessel to ambient conditions; and

recovering a biological vehicle with bound cargo molecule.

(Appeal Br. 18.)

The Examiner rejects the claims as follows[3]:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Final Office Action
1, 6, 21	102(a)(1)	Truong-Le[4]	3–5
1, 6, 21, 22	102(a)(1)	Christensen[5]	8–12
1, 6	Nonstatutory double patenting	Claims 1–9 of Christensen	15–17

ANALYSIS

Claims 1, 6, 21, and 22 anticipated by Christensen

The Examiner finds Christensen discloses a method including the steps of mixing a biological vehicle, e.g., spores, with a cargo molecule, e.g.,

[3] The Examiner's rejections based on Christopher et al., U.S. Patent 7,771,652 B2 were withdrawn.
[4] Truong-Le et al., U.S. Patent 7,258,873 B2, issued August 21, 2007.
[5] Christensen, U.S. Patent 7,919,096 B2, issued April 5, 2011.

natural or synthetic compounds, in a fluid, and subjecting the fluid mixture to subcritical or supercritical carbon dioxide. (Final Act. 8.) The Examiner finds that Christensen discloses filtering the fluid, thereby separating excess cargo molecules from the biological vehicle. (*Id.* at 8–9.) The Examiner finds that Christensen's process inherently results in the step of "affect[ing] the surface of the biological vehicle allowing the cargo molecule to bind to and penetrate the biological vehicle." (*Id.* at 9.) As to claim 22, which recites the closed transitional phrase "consisting of," the Examiner finds Christensen does not include any additional steps excluded by the claimed process. (*Id.*) Accordingly, the Examiner concludes Christensen anticipates the claims. (*Id.* at 10.)

Appellant contends that Christensen does not disclose contacting biological vehicles with subcritical or supercritical fluid to affect penetration by a cargo molecule. (Appeal Br. 14.) Rather, Appellant contends that "Christensen discloses contacting microorganisms with subcritical or supercritical fluid for the purpose of sterilization." (*Id.*) Appellant contends that without subjecting the mixture to subcritical or supercritical fluid to affect the surface of the biological vehicle, it is impossible to perform the last step of recovering a biological vehicle with bound cargo molecule. (*Id.* at 10.)

We are not persuaded by Appellant's argument. As found by the Examiner, Christensen teaches the same process as claimed, including the steps of: (1) mixing spores with a natural compound additive, e.g., yeast extract, or synthetic compound additive, e.g., acetic acid or formic acid, in a suspension; (2) placing the mixture inside a pressure vehicle; (3) subjecting

the mixture to a supercritical fluid; (3) returning the pressure and temperature to ambient conditions; and (4) removing the additive and collecting the treated spores. (Christensen 10:50–11:13, 12:5–17 (Example 5).) Christensen does not disclose that the additives bind to and penetrate the spores, and thus, Appellant may have identified a previously unknown result of the prior art process. However, "merely discovering and claiming a new benefit of an *old* process cannot render the process again patentable." *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990).

Where the claimed and prior art processes are substantially identical, the PTO can require an applicant to prove that the prior art process does not necessarily or inherently result in the same product as the claimed process. *See In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). Appellant has not provided any evidence showing that Christensen's process does not necessarily result in the same biological vehicle with bound cargo molecule. Absent evidence to the contrary, we agree with the Examiner that Christensen inherently anticipates claim 1.

Appellant separately argues claim 6. (Appeal Br. 14.) Appellant contends that Christensen's disclosure of a filter for the pressure vessel does not disclose separating a biological vehicle with a bound cargo molecule from excess cargo molecules. (*Id.* at 14–15.)

We are not persuaded by Appellant's argument. In rejecting claim 6, the Examiner cites Christensen at Example 5 and column 8. (*See* Final Act. 8–9.) As found by the Examiner, Christensen teaches a filter for separating liquid additive, i.e., cargo molecules, from a container for holding treated organisms, i.e., biological vehicle. (Christensen 8:30–35, 50–53.)

Moreover, Christensen's Comparative Example 5 repeats the process of Example 3A, except with different chemical additives, i.e., cargo molecules. (*Id.* at 12:8–10.) Christensen's Example 3A discloses treating the spore and additive mixture with supercritical carbon dioxide, then removing the additive and collecting the treated spores. (*Id.* at 11:4–11.) Accordingly, Christensen discloses separating the biological vehicle with bound cargo molecules from excess cargo molecules, and thus anticipates claim 6.

Appellant argues independent claim 22 separately. (Appeal Br. 15.) Appellant contends that Christensen requires the step of sterilizing the organism, which is excluded from claim 22 by the closed transitional phrase "consisting of." (*Id.*)

We are not persuaded by Appellant's argument for two reasons. First, we do not agree that the broadest reasonable interpretation of claim 22 excludes sterilization as a result of the claimed process. As the Examiner finds, claim 22 does not exclude a sterilant from the listed cargo molecules, which include natural and synthetic compounds. (Ans. 16.) The Specification supports this finding by disclosing that "the present process can also incorporate a sterilant where it is desired to produce impregnated inactivated organisms." (Spec. 22.) Using a sterilant as the cargo molecule in the process of claim 22 would result in sterilizing the biological vehicle as part of the subjecting step, regardless if the result is expressly claimed.

Second, Christensen discloses that none of the additives evaluated in Example 5 were effective in achieving at least a 6-log reduction in colony forming units of the tested spores. (Christensen 12:26–28.) Therefore, Christensen discloses a process that does not include sterilization. Because

the Examiner has identified the same process in the prior art and Appellant has not provided evidence that the prior art produces a different result, we sustain the Examiner's rejection of the claims as anticipated by Christensen.

Claims 1, 6, and 21 anticipated by Truong-Le

The Examiner finds Truong-Le discloses a method including the steps of: (1) mixing bioactive materials, e.g., bacteria, cells, or viruses, with natural compounds, e.g., trehalose, in a solution; (2) exposing the mixture to subcritical or supercritical carbon dioxide; (3) reducing the pressure; and (4) recovering the treated bioactive material. (Final Act. 3.) The Examiner finds that the treated bioactive material forms particles that are separated from unbound cargo molecules. (*Id.*) The Examiner finds that Truong-Le's process inherently results in affecting the surface of the biologic vehicle allowing the cargo molecule to bind and penetrate the biological vehicle. (*Id.* at 3–4.)

Appellant contends that the process of Truong-Le is distinct from the claimed process, and thus does not result in affecting the surface of the biological vehicle allowing the cargo molecule to bind and to penetrate the biological vehicle. (Appeal Br. 12.) Specifically, Appellant contends Truong-Le's process forms a bioactive solution which is mixed with a near supercritical fluid. (*Id.* at 11.) Appellant contends that Truong-Le's mixture of bioactive solution and near supercritical fluid is then sprayed into liquid droplets under reduced pressure and subjected to a drying gas to form powder particles. (*Id.* at 12.) Appellant contrasts the claimed method, contending that the subcritical or supercritical fluid does not mix with the

suspension of biological vehicle and cargo molecule and, instead, the fluid is released when the pressure is reduced. (*Id.*)

We are not persuaded by Appellant's arguments. Truong-Le teaches combining either suspensions or solutions of bioactive material and a polyol with near supercritical fluid. (Truong-Le 3:16–20.) Moreover, Truong-Le's steps are the same as the broadest reasonable interpretation of Appellant's claim 1. For example Truong-Le's step of mixing the bioactive suspension with a near supercritical fluid discloses the step in claim 1 of "subjecting the cargo molecule and biological vehicle mixture to subcritical or supercritical fluid." Likewise, Truong-Le's steps of: (1) spraying under reduced pressure discloses "returning pressure and temperature within the pressure vessel to ambient conditions;" and (2) collecting particles discloses "recovering a biological vehicle with bound cargo molecule." (*Id.* at 3:20–21, 5:25–27.) As to claim 6, Truong-Le discloses separating particles by particle size, which necessarily separates larger particles (biological vehicle with bound cargo molecule) from small particles (excess cargo molecules). (*Id.* at 22:19–30.)

Because Truong-Le discloses the same method under the broadest reasonable interpretation of the claims, Appellant has the burden to provide evidence showing Truong-Le's method does not inherently "affect the surface of the biological vehicle allowing the cargo molecule to bind to and penetrate the biological vehicle." *See Best*, 562 F.2d at 1255. Appellant argues that the Truong-Le's method results in a "fundamentally different" product. (Appeal Br. 10–11.) However, as the Examiner finds, Appellant's attorney argument is no substitute for evidence. *Johnston v. IVAC Corp.*,

885 F.2d 1574, 1581 (Fed. Cir. 1989). Absent evidence to the contrary, we are not persuaded that the Examiner erred, and we sustain the Examiner's rejection of claims 1, 6, and 21 as anticipated by Truong-Le.

Claims 1 and 6: Nonstatutory double patenting

The Examiner finds claims 1 and 6 are not patentably distinct over claims 1–9 of Christensen. (Final Act. 15–17.) The Examiner finds that Christensen's claims 1–9 are drawn to a method "comprising contacting [*i.e.,* mixing] whole microorganisms [*i.e.,* biological vehicles] with a fluid comprised of carbon dioxide at or near its supercritical pressure and temperature conditions and wherein said fluid is further comprised of a chemical additive [i.e., a cargo molecule; a natural or synthetic compound] . . . ." (*Id.* at 16.) As discussed above, the Examiner finds that the prior art method inherently results in affecting the surface of the biological vehicle allowing the cargo molecule to bind to and penetrate the biological vehicle. (*Id.*)

Appellant contends that instant claims 1 and 6 are patentably distinct from Christensen's claims 1–9 because the instant claims do not claim reducing the infectivity and/or pathogenicity of microorganisms. (Appeal Br. 16.)

We are not persuaded by Appellant's argument. Christensen's claims are drawn to the same process as claims 1 and 6, although with a different claimed result, namely sterilization rather than impregnation. (*See* Christensen 16:16–62 (claims 1–9).) However, both claimed results appear to be inherent to the process itself. Moreover, the broadest reasonable

interpretation of Appellant's claims 1 and 6 does not exclude sterilization as a result of the claimed process. (*See above* as to claim 22.) Accordingly, we agree with the Examiner that the claims are not patentably distinct and sustain the rejection of claims 1 and 6 for nonstatutory double patenting.

CONCLUSION

Upon consideration of the record and for the reasons given, we affirm the Examiner's rejections.

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 6, 21	102(a)(1)	Truong-Le	1, 6, 21	
1, 6, 21, 22	102(a)(1)	Christensen	1, 6, 21, 22	
1, 6		Nonstatutory Double Patenting	1, 6	
Overall Outcome			1, 6, 21, 22	

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

AFFIRMED