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McCarter & English, LLP/LifeCell 265 Franklin Street Boston, MA 02110			KIPOUROS, HOLLY MICHAELA	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BENJAMIN T. KIBALO

Appeal 2019–003943
Application 14/676,289
Technology Center 1700

Before MONTÉ T. SQUIRE, AVELYN M. ROSS, and
BRIAN D. RANGE, *Administrative Patent Judges*.

RANGE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant appeals from the Examiner’s decision to reject claims 59–70, 72, and 74.¹ We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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 LifeCell Corporation. Appeal Br. 1.

CLAIMED SUBJECT MATTER²

Appellant describes the invention as relating to processing of human or animal tissue for patient issue. Spec. ¶ 2. In particular, tissues are processed to remove certain components or destroy pathogens while maintaining desired biologic properties of the tissue. *Id.* ¶¶ 2, 23. Claim 59 is the only independent claim on appeal and is illustrative of the claimed subject matter:

59. A method for reducing the bioburden in a soft tissue sample, said method comprising:

providing a tissue comprising mammalian skin;
removing an epidermal layer from the skin; and

applying a sustained pressure to the tissue by **placing the tissue in a liquid** and applying sustained elevated pressure to the liquid for a time sufficient to cause at least a 5 log reduction in the bacterial concentration within the tissue, wherein the pressure is applied at a rate to control the temperature of the tissue such that the temperature of the tissue does not exceed 30°C.

Appeal Br. 13 (Claims App.) (emphasis added to certain key recitations).

² In this Decision, we refer to the Final Office Action mailed May 1, 2018 (“Final Act.”), the Appeal Brief filed October 29, 2018 (“Appeal Br.”), the Examiner’s Answer mailed February 25, 2019 (“Ans.”), and the Reply Brief filed April 23, 2019 (“Reply Br.”).

REFERENCES

The Examiner relies upon the prior art below in rejecting the claims on appeal:

Mills et al. ("Mills")	US 2006/0228252 A1	Oct. 12, 2006
Ngo et al. ("Ngo")	US 2010/0323440 A1	Dec. 23, 2010
Kibalo	US 9,023,273 B2	May 5, 2015
Kishida et al. ("Kishida")	WO 2008/111530 A1	Sept. 18, 2008

REJECTIONS

- The Examiner maintains (Ans. 3) the following rejections on appeal:
- A. Claims 59–70 and 72 on the ground of nonstatutory double patenting type obviousness as being unpatentable over claims 1–14 of Kibalo. Final Act. 4–5.³
 - B. Claims 59–65 and 74 under 35 U.S.C. § 103(a) as obvious over Ngo in view of Kishida. *Id.* at 5–9.
 - C. Claims 66–70 under 35 U.S.C. § 103(a) as obvious over Ngo in view of Kishida and Mills. *Id.* at 9–11.
 - D. Claim 72 under 35 U.S.C. § 103(a) as obvious over Ngo in view of Kishida and Sun. *Id.* at 11.

³ The rejection does not address claim 74. In the event of further prosecution, we leave application of nonstatutory double patenting to claim 74 for the Examiner to address in the first instance.

OPINION

We review the appealed rejections for error based upon the issues identified by Appellant and in light of the arguments and evidence produced thereon. *Ex parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010) (precedential), *cited with approval in In re Jung*, 637 F.3d 1356, 1365 (Fed. Cir. 2011) (“[I]t has long been the Board’s practice to require an applicant to identify the alleged error in the examiner’s rejections.”). After considering the evidence presented in this Appeal and each of Appellant’s arguments, we are not persuaded that Appellant identifies reversible error. Thus, we affirm the Examiner’s rejections for the reasons expressed in the Final Office Action and the Answer. We add the following primarily for emphasis.

Rejection A, non-statutory double patenting. Appellant does not address this rejection. We, therefore, summarily affirm the rejection.

Rejections B, C, and D, obviousness. Appellant does not present substantively separate arguments for these rejections and does not argue any claim recitations other than those of independent claim 59. Appeal Br. 7–12. We therefore limit our discussion to claim 59. All other claims stand or fall with that claim. *See* 37 C.F.R. § 41.37(c)(1)(iv).

The Examiner finds that Ngo teaches providing a tissue sample comprising mammalian skin, removing an epidermal layer from the skin, applying sustained pressure for time sufficient to sterilize the tissue, and maintaining the temperature below 30°C during application of the elevated pressure. Final Act. 5–6 (citing Ngo). The Examiner finds that Ngo does not teach applying the elevated pressure by placing the tissue in liquid. *Id.* at 7. The Examiner finds, however, that Kishida teaches preparing a soft tissue sample for transplantation by applying sustained elevated pressure by

placing the tissue in liquid. *Id.* (citing Kishida). The Examiner also finds that Kishida teaches that its method disrupts bacteria in the tissue while also advantageously preventing unwanted swelling of the tissue. Ans. 5–6 (citing Kishida). The Examiner determines that a person of skill in the art would have applied the teachings of Kishida (use of a liquid) to achieve the elevated pressure of Ngo teaches because Kishida’s method “is recognized in the art to be effective in reducing bioburden while avoiding damage to the tissue.” Final Act. 8.

Appellant argues that a person of skill in the art would not have modified Ngo with Kishida because Ngo requires use of supercritical carbon dioxide during its application of pressure. Appeal Br. 7–11. The Examiner disagrees by finding that Ngo teaches two distinct methods. Ans. 4. The Examiner explains that the rejection is based only on Ngo’s second method—a method that does not require supercritical carbon dioxide.

As summarized below, the preponderance of the evidence supports the Examiner’s position that Ngo teaches two methods and that the second method does not require supercritical carbon dioxide. Ngo’s title, “PROCESS FOR STERILIZING ACELLULAR SOFT TISSUE UNDER PRESSURE,” does not reference supercritical carbon dioxide. Ngo’s abstract likewise does not reference supercritical carbon dioxide. Ngo’s Figure 1 is a schematic flow chart of Ngo’s process (Ngo ¶ 23), and Figure 1 indicates that “SUPER CRITICAL CO₂” and “ULTRA HIGH PRESSURE” are distinct alternative final steps of the Ngo process. Ngo’s Summary of the Invention also does not reference supercritical carbon dioxide. *Id.* ¶¶ 12–22.

Ngo’s more detailed explanation of its two examples indicates the examples are distinct. Ngo example 1 is entitled “Sterilization of Dermis **with Supercritical CO₂ Under Pressure**,” and example 1’s final step states “[t]he dermis is then treated with supercritical CO₂ under pressure from about 1400 to 2000 psi.” *Id.* ¶¶ 33–42 (emphasis added). In contrast, Ngo example 2 is entitled “Sterilization of Dermis **with Ultra High Pressure**,” and example 2’s final step states “[t]he dermis is then sterilized under ultra high pressure.” *Id.* ¶¶ 43–53 (emphasis added). Ngo’s second example does not reference supercritical carbon dioxide. The different language of these two examples suggests that the “Ultra High Pressure” example (example 2) does not make use of supercritical carbon dioxide.

Appellant emphasizes Ngo paragraph 32. Appeal Br. 10–11; *see also* Reply Br. 3. That paragraph states the “dermis is [then] sterilized with supercritical CO₂ at a temperature ranging from 10 ° C–80° C at a pressure ranging from 1200–2200 psi for a period ranging from about 10 to about 200 minutes **or is alternatively** sterilized under ultra high pressure ranging from 65,000–125,000 psi at a temperature ranging from -10° C–30° C for a period ranging from 1–30 minutes.” Ngo ¶ 32 (emphasis added). In view of the other context Ngo provides, as discussed above, this paragraph is best understood as stating that “supercritical carbon dioxide” and “ultra high pressure” are alternative and distinct sterilization methods. *Id.*

Because Ngo teaches an “ultra high pressure” method (i.e., method 2) that does not involve supercritical CO₂, a person of skill in the art would naturally look to other references to ascertain how to implement the ultra high pressure method. *Id.* The teachings of Kishida provide such an implementation with the advantage of, for example, preventing swelling of

the tissue. Ans. 6. Appellant's argument, therefore, does not identify error in the Examiner's rejections, and we sustain the rejections.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
59-70, 72		Obviousness-type double patenting, Kibalo	59-70, 72	
59-65, 74	103	Ngo, Kishida	59-65, 74	
66-70	103	Ngo, Kishida, Mills	66-70	
72	103	Ngo, Kishida, Sun	72	
Overall Outcome			59-70, 72, 74	

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