IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS
Petitioner

v.

AKER BIOMARINE ANTARCTIC AS
Patent Owner

CASE: IPR2018-01730

U.S. Patent No. 9,072,752

Reply Declaration of Dr. Nils Hoem in Support of Patent Owner's Motion to Amend

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I. Introduction

I, Dr. Nils Hoem, state as follows:

1. I make this declaration in support of Patent Owner's Contingent Motion to Amend the Claims in IPR2018-01730 and in Reply to Petitioner's Opposition of the Contingent Motion to Amend the Claims.

2. I have reviewed and considered, in the preparation of this report, the documents below in addition to the documents identified in my first declaration (Ex. 2001). In providing this declaration, I have also used the legal standards set forth in my first declaration.

EXHIBIT NO.	EXHIBIT DESCRIPTION
1086	Reply and Opposition Declaration of Dr Stephen J. Tallon (IPR2018-01730)

II. The Contingent Amended Claims are Not Obvious

3. I stand by my previous opinion that the contingent amended claims are not obvious. I have been informed that Petitioner alleges that the amended claims are obvious over the following combinations of references:

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Ground 1. Claims 21 and 24-27 are obvious over Catchpole, Sampalis II, NKO and Randolph;

Ground 2. Claims 22-23, 25, and 28-29 are obvious over Catchpole, Enzymotec, Sampalis II, NKO and Randolph; and

Ground 3. Claims 21-29 are obvious over Catchpole, Enzymotec, Sampalis II, NKO and Randolph.

4. The data in Catchpole demonstrates that the impact of altering extraction conditions such as the co-solvent concentration in SFE extraction procedures is unpredictable. Examples 7 and 8 of Catchpole describes SFE fractionation of "dairy lipid extract B." I first note that the phospholipid makeup of the dairy lipid extract B is different from the krill feed material used in Example 18 and contains, for example, more PE (phosphatidylethanolamine) than PC (phosphatidylcholine), and substantial amounts of PS (phosphatidylserine) and SM (sphingomyelin). The krill feed material contained much higher levels of PC than PE, and had no reported PS or SM. Thus, comparison of the results of Example 7 and 8 to the results of Example 18 is confounded by the differences in the feed materials.

5. With that being said, Examples 7 and 8 both use a two-step extraction with neat CO_2 in the first step and an CO_2 plus an ethanol co-solvent in the second

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step. Example 7 used an ethanol co-solvent at a concentration of 10% while Example 8 used an ethanol co-solvent at a concentration of 30%. The extract obtained with the ethanol co-solvent at a 30% concentration contained more PC than the feed material (22.5%) and more PC as compared to extract 2 of Example 8, which contained 4.5% PC. However, Example 10 describes fractionation of egg yolk lecithin, also using a two step SFE procedure using neat CO_2 in the first step and an ethanol co-solvent in the second step at a concentration of 25%. In Example 10, the feed material is also different from the feed materials in Examples 7, 8 and 18 and is reported to contain 56.4% PC. In contrast to Example 8, the extract obtained with the 25% ethanol co-solvent contained a reduced amount of PC (43.5%) as compared to the feed material. This is despite extracting a reported 45% of the initial feed material as neutral lipids in the first step. These results demonstrate that it is unpredictable as to whether using ethanol co-solvents in excess of 20% will result in fractionation of a feed material so that the PC content is increased. The Tables from Examples 7 (Table 7), 8 (Table 8) and 10 (Table 9) are reproduced here for reference:

Table 7

	Yield % of feed	Composition, %						
		PC	PI	PS	PE	SM	Other Phospholipids	Other compounds
Feed		7.4	2.5	3.9	10.3	5.7	1.3	69.0
Extract 2	3	4.5	0.0	0.0	1.6	1.0	0.3	92.6
Residue	45	15.0	6.1	8.7	21.8	12.0	5.9	30.7

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Table 8

	Yield % of feed	Composition, %						
		PC	PI	PS	PE	SM	Other Phospholipids	Other compounds
Feed		7.4	2.5	3.9	10.3	5.7	1.3	69.0
Extract (2)	7	22.5	0.5	0.4	14.0	11.2	3.3	48.2
Residue	41	12.0	5.5	8.5	20.2	10.0	2.4	41.5

Table 9

	Yield % of feed	Composition, %						
		PC	PI	PS	PE	SM	Other Phospholipids	Other compounds
Feed		56.4	N/D	N/D	6.4	2.0	5.7	29.4
Extract	49	43.5	N/D	N/D	9.2	2.6	2.1	42.5
Residue	6	17.4	8.0	5.9	19.1	3.8	3.8	42.0

6. The results obtained in Examples 12 and 18 of Catchpole also demonstrate the unpredictability associated with different feed materials and extraction conditions. Example 12 describes the fractionation of a Hoki head lipid extract by a two-step SFE method using neat CO_2 in the first step and an ethanol co-solvent in the second step at a concentration of 31%. Example 18 describes fractionation of krill lipids from a freeze-dried krill powder feed material by a two-step SFE method using neat CO_2 in the first step and an ethanol co-solvent in the second step at a concentration of 11%. Table 11 (Example 12, Hoki head) and Table 18 (Example 18, krill lipids) are reproduced below for reference.

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