

EXHIBIT 21

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LEO J. ROMANCZYK
 [Signature]

New Docket No. 5677/196
(Continuation of 5677/167)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Continuation Application of: Leo J. Romanczyk, Jr. et al.

Serial No. : To be assigned Group Art Unit : (former Art Unit 1711)
 Filed : Herewith Examiner : (former Examiner N. Nutter)
 For : COCOA EXTRACTS CONTAINING SOLVENT-DERIVED COCOA POLYPHENOLS FROM DEFATTED COCOA BEANS

Commissioner for Patents
Box: Patent Application
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sirs:

Please amend the application as follows:

In the Specification

Please cancel the title "SOLID COMPOSITIONS AND LIQUID PREPARATIONS FOR ORAL ADMINISTRATION WHICH CONTAIN COCOA POLYPHENOLS" and insert the title --COCOA EXTRACTS CONTAINING SOLVENT-DERIVED COCOA POLYPHENOLS FROM DEFATTED COCOA BEANS--.

Please add the following sentence after the Title and before the Background of the Invention:

-- This application is a continuation of Serial No. 09/975,242, filed October 11, 2001, *and* *US Patent 6,517,841* now allowed, which is a continuation of Serial No. 09/768,473 filed January 24, 2001, now *US Patent No. 6,562,863* allowed, which is continuation of Serial No. 09/172,873 filed October 15, 1998, now U.S. Patent No. 6,225,338 issued May 1, 2001, which is a division of Serial No. 08/839,446 filed April 14, 1997, now U.S. Patent 5,891,905 issued April 6, 1999, which is a division of Serial No. 08/687,885 filed July 26, 1996, now U.S. Patent No. 5,712,305 issued January 27, 1998, which is a division of Serial No. 08/317,226 filed October 3, 1994, now U.S. Patent No. 5,554,645 issued September 10, 1996. --

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In the Claims

sed

Please cancel Claim 27 of the prior application Ser. No. 09/975,242 which was retained for purposes of copendency.

Please add the following new claims which are numbered starting with the next highest number after the last claim in the first filed application. If the claims are incorrectly numbered, please contact the undersigned or renumber the claims.

Subcl
27
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- 27. A crude cocoa extract comprising at least one solvent-derived cocoa polyphenol.
- 28. The extract of Claim 27, wherein the cocoa extract comprises a mixture of cocoa polyphenols.
- 29. The extract of Claim 28, wherein the cocoa polyphenols comprise catechin, epicatechin, and procyanidin oligomers thereof.
- 30. The extract of Claim 29, wherein the oligomers are dimers through dodecamers.

Sub 101 Cont.

31. The extract of Claim 27, wherein the crude cocoa extract is fractionated into monomeric and oligomeric fractions.

32. The extract of Claim 31, wherein the monomeric fractions comprise epicatechin and catechin.

33. The extract of Claim 31, wherein the oligomeric fractions comprise cocoa procyanidins selected from the group consisting of dimers through dodecamers.

~~34. The extract of Claim 31, wherein the fractions are pooled fractions.~~

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35. The extract of Claim 27, which is prepared from defatted, freeze dried cocoa beans.

36. The extract of Claim 35, wherein the cocoa beans are fermented.

37. The extract of Claim 35, wherein the cocoa beans are unfermented.

38. The extract of Claim 37, wherein the cocoa beans are selected from the group consisting of Trinitaro, Forastero, and Criollo cocoa beans.

39. The extract of Claim 27, which is purified by gel permeation chromatography.

40. The extract of Claim 27, which is purified by preparative high performance liquid chromatography.

41. The extract of Claim 39, which is purified by preparative high performance liquid chromatography.

42. The extract of Claim 40, wherein the preparative high performance liquid chromatography is reverse phase preparative high performance liquid chromatography.

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43. The extract of Claim 41, wherein the preparative high performance liquid chromatography is normal phase preparative high performance liquid chromatography.

*Subject
cont.*

~~44. The extract of Claim 27, wherein the solvent comprises acetone and water, methanol and water, or ethyl acetate.~~

45. The extract of Claim 44, wherein the solvent is acetone and water.

46. The extract of Claim 44, wherein the solvent is methanol and water.

47. The extract of Claim 44, wherein the solvent is ethyl acetate.

*a.g.
cont.*

~~48. The extract of Claim 27 in liquid form.~~

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~~49. The extract of Claim 27 in dry form.~~

50. The extract of Claim 49 in lyophilized form.

REMARKS

Support for a "crude cocoa extract" may be found in Example 2, Table 2 where the crude procyanidin yields are reported. See also Method 2 of Example 2 where it is reported that the yields of crude procyanidins ranged from 15-20% and Example 3 which discloses the partial purification of the crude procyanidins of Example 2. See also Figure 15K and the reference to "crude extracts of . . . cocoa polyphenols".

Support for the cocoa extract containing "at least one solvent-derived cocoa polyphenol" can be found at page 12, lines 17-19 where the extracts are identified as "cocoa polypheno(s)" and in Example 2, where aqueous acetone and aqueous methanol were used as the solvents for the extraction.

For support for the polyphenols comprising "catechin, epicatechin, and procyanidin oligomers" see Figure 2A.

For support for "dimers through dodecamers" see Table 3.

Support for "cocoa procyanidins comprise monomeric and/or oligomeric fractions" may be found in Figures 2A and 2B and for support for "pooled fractions" see Example 9, where combined fractions A through C and D and E were used as well as Table 6 where various pooled fractions are shown.

Support for the use of a defatted cocoa mass for the solvent extraction may be found in Example 2, Methods A and B which shows that the extracts were obtained from a defatted cocoa mass using acetone/water and/or methanol/water as the extraction solvents.

Support for the use of "fermented cocoa beans" can be found in Fig. 15L where the cells were "...treated with crude polyphenol extracts obtained from fermented cocoa beans and dried cocoa beans (stages throughout fermentation and sun drying;..." as well as the text at page 38, lines 19-22 (see reference to "traditional 5-day fermentation of Brazilian cocoa beans").

Support for the use of "unfermented cocoa beans" can be found in Example 2.

Support for "solvent extraction of defatted cocoa beans" may be in Example 2 as well as at page 12, lines 6-9. Support for the solvents being "acetone and water" and "methanol and water" may be found at page 16, lines 17-20 and for the solvent being "ethyl acetate" may be found at page 16, lines 25, 26.

Support for "purified by gel permeation chromatography", purified by "high performance liquid chromatography", and "reverse phase" and "normal phase separation may be found in Example 3, Part B, Methods 1 and 2.


Support for the cocoa extract "in liquid form" may be found in the examples, particularly Examples 2 and 3.

Support for the cocoa extract in dry form, i.e., a "lyophilized" extract, can be found at page 13, lines 28-30.

Entry of this Preliminary Amendment is respectfully requested. No new matter is presented.

A marked-up version showing changes is attached.

Respectfully submitted,


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MARKED-UP VERSION SHOWING CHANGES

In the Specification

Please cancel the title [SOLID COMPOSITIONS AND LIQUID PREPARATIONS FOR ORAL ADMINISTRATION WHICH CONTAIN COCOA POLYPHENOLS] and insert the title COCOA EXTRACTS CONTAINING SOLVENT-DERIVED COCOA POLYPHENOLS FROM DEFATTED COCOA BEANS.

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