# Third Party Observation for application Number EP20180874683

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**Title: METHOD FOR PROCESSING RAW SUGARCANE MAXIMIZING THE PRESERVATION OF POLICOSANOLS DURING PRODUCTION OF A NATURAL SUGARCANE JUICE-BASED PRODUCT**

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## 1. Facts and evidence

### 1.1. Reference is made to the following documents

PL1 US6,245,153 12.06.2001 Method for producing sugar cane juice

PL2 US8,828,142 09.09.2014 Processes for extraction of sugar from sugar-bearing plant material

PL3

### 1.2. Observations concerning the public availability of the non-patent literature

NPL1

MANEJO DE JUGOS DE CAÑA Y ELABORACIÓN DE PANELA DE BUENA CALIDAD 1997(Albio E. Espinosa Safar )

Uploaded documents:

1. NPL1_200828 LP1.pdf

NPL2

MANEJO DE LOS JUGOS DE CAÑA PARA LA ELABORACIÓN DE PANELA Y MIELES 2001(Roberto Manrique E., Luz Esperanza Prada and Saul Bernardo Aguiar)

Uploaded documents:

1. NPL2_200828 LP2.pdf

NPL3

Diversificación de la agroindustria panelera en la producción de mieles invertidas 9/03/2017(María Consuelo Quiroga Maldonado, Heidy Guillen Pedraza, Jorge Camilo Guerrero Morales, Diana Carolina Jiménez, José Hernando Ruiz Barragán)

Uploaded documents:

1. NPL3_200828 LP3.pdf

NPL4

Efectos de la presión de evaporación y la concentración de antiespumante y del uso de floculante y coadyuvante en la calidad de la miel y la panela 2014(Luz Esperanza Prada Forero, Hugo Reinel García Bernal, Arlex Chaves Guerrero)

Uploaded documents:

1. NPL4_200828 LP4.pdf

NPL5

Policosanol contents, volatile profile and toxicity test of granulated cane sugar enriched with rice bran materials June 2017(Weerawatanakorn, M., Tamaki, H., Asikin, Y., Wada, K., Takahashi, M.,Ho, C.T. and Pan, M.H.)

Uploaded documents:

1. NPL5_200828 LP5.pdf

## 2. Prior Use

### 2.1. Prior use (1)

**When did the prior use occur?**

**What was made available?**

**Where was it made available?**

**How and to whom was it made available?**

## 3. Common General Knowledge

The method for processing sugar cane in Colombia (and other parts of the world) is well-known in the field and vastly documented in the world (since similar products are produced and consumed in different parts of the world like Japan, Thailand, Vietnam, India, South America, several countries in Central America, and, in particular, in Colombia, being the second largest producer in the world). Non-centrifugal sugar (NCS) is the common name of this method, wherein the collected sugar cane is cut, milled and macromolecules are removed to produce a sugar cane juice that is later clarified, evaporated and concentrated. The juice resulting from this method can be further treated to produce a sugar cane honey or it could be molded to be commercialized as "panela". During this ancestral and traditional process known and developed by farmers and peasants several centuries ago in Colombia, policosanols (PC), naturally occurring in the cortex of sugar cane, are extracted therefrom and are part of the resulting panela product.

## 4. Novelty (Article 54 EPC)

### 4.1. Novelty (1)

## 5. Inventive step (Article 56 EPC)

### 5.1. Inventive step (1)

**Features known from the prior art:**

In the instant case, the closest prior art document is PL1. This patent discloses a method for producing sugar cane juice which is on the same field of application No. EP20180874683 (published as EP3678678A1). As it will be demonstrated below, the method disclosed in PL1 is almost identical to the one recited in application No. EP20180874683. The problem solved by PL1 is providing a method for producing stable sugar cane juice for bottling and distribution.

The method disclosed in PL1 comprises the following steps:

- Harvesting and transporting sugar cane: PL1 discloses a method for manually cutting sugar cane at two inches from the stool, removing all green and dry leaves (or "cogollos"), which is later transported to the processing facility (column 2, lines 61 to 67);
- Chopping and juice extraction: at this stage, PL1 teaches that sugar cane is further cut to smaller pieces that are introduced in a series of roller millers, from which a sugar cane juice is extracted (column 3, lines 27 to 30);
- Macro-particle filtration: a standard filtration process is carried out in the sugar cane juice extracted from the roller mills to remove any macroparticles using a standard steel screen filter (column 3, lines 56 to 58 and 61 to 65);
- pH stabilization: at this stage, PL1 discloses the addition of calcium hydroxide (known as limewater or milk of lime) until the pH is of about 7.5 (column 4, lines 4 to 7, 10 to 16);
- Heating: this process occurs after the pH of the juice is stabilized from about 26.7 to 29.4°C to about 99°C (column 4, lines 29 to 32);
- First clarification: at this stage, flocculating agents are added to the juice (from natural or industrial origin well-known in the field), so flocculates are formed and extracted from the juice (column 4, lines 49 to 60);
- Second clarification: this process is carried in a particular apparatus disclosed in the patent using a flocculating agent from

natural sources (GUASIMO (GUAZUMA ULMIFO LIA LAMARK); BALSO (OCHOMALAGOPUSSW); and CADILLO (TRIUMFETTA LAPPULAL), which helps in maintaining the juice' natural flavor. Addition of the flocculating agent causes the formation of a froth commonly known as "cachaza," which floats on the surface of the juice (column 5, lines 38 to 43 and 52 to 57);

- Evaporation and extraction: following clarification, the juice is evaporated through sugar mill evaporators to increase the concentration of sugar cane juice at a Brix of 60 decrees (60°Br) (column 6, lines 36 to 44).

After the above steps, PL1 discloses a third clarification and vacuum steps, to a cooling & settling step, achieving a juice of 75°Br.

**Novel features not known from the prior art:**

Claim 1 from Application No. EP20180874683 recites a method for processing raw sugarcane sticks. Claim 1 differs from PL1 in (i) a surfactant is introduced into the extraction sugarcane system prior to the first roller mill, and (ii) a proviso in Claim 1 according to which the processing method precludes the juice product from exceeding 90°C throughout the process.

**The technical effect caused or technical problems solved by the novel features:**

From reviewing the application there is not a single example or evidence demonstrating that the above-mentioned differences provide any technical effect, in particular, wherein there is a method disclosing almost all of the steps of the claimed method.

Claim 1 of Application No. EP20180874683 states that temperatures above 90°C are to be avoided throughout the process in order to "minimize evaporation of policosanols therefrom". Paragraphs [0017], [0030], [0037], [0067], [0104] and [0116] of Application No. EP3678678A1 teach that temperature should not exceed 90°C (even though paragraph [0037] states that temperature in the heating step should never exceed 95°C) in order to avoid the loss of policosanols. According to paragraph [0030], controlling the temperature is crucial departure from conventional methods, wherein maintenance of policosanols was not relevant.

However, the process in which policosanols are lost is not completely disclosed in application EP3678678A1. In fact, application EP3678678A1 does not provide a single result demonstrating that following the process disclosed and recited therein, a particular level or percentage of policosanols are maintained. Neither does this application disclose the amount or percentage of policosanols in the different sugar cane products that use the enriched sugar cane juice resulting from the claimed method.

Therefore, Application No. EP3678678A1 does not provide evidence demonstrating that (i) indeed, extraction processes that carry out the same steps as claimed with higher temperatures (99°C-120°C) result in sugar cane juice with lower amounts of policosanols, and (ii) more importantly, that the claimed method indeed results in policosanols enriched sugar cane products.

Similarly, and given the similarities of the method disclosed in PL1, Application No. EP3678678A1 do not provide comparative results demonstrating that the differences between the method of PL1 and Claim 1 indeed result in a technical effect. Thus, there is not technical effect caused by the novel feature.

Additionally, it is worth pointing out that inventions are, by definition, novel and inventive solutions to a technical problem. In this case, even though Application No. EP3678678A1 states that the problem to be solved therein is providing "a repeatable, efficient, and highly cost-effective process for the commercial production of a policosanol-rich, stable, consumable product from raw sugarcane," there is no evidence whatsoever in the Specification demonstrating that the problem was indeed solved by the method, since it does not provide a single example illustrating the percentage of policosanols in the product obtained from the claimed method. Thus, it cannot be concluded that the problem was actually solved by the method recited in Application No. EP3678678A1.

**Reasons why it would be obvious to the skilled persons to combine the features as set in the independent claim:**

Claim 1 of Application No. EP3678678A1 a method for processing a quantity of raw sugarcane sticks to produce a policosanol-rich sugarcane-based concentrate via a sugarcane juice product processing system, comprising steps of:

- shredding said sugar cane sticks and introducing said shredded sugarcane sticks to a series of mechanical roller mills;

- extracting sugarcane juice from said shredded sugarcane sticks via said series of roller mills, wherein a quantity of a surfactant is introduced into the system at a system location prior to said first roller mill;
- filtering said extracted sugarcane juice through at least one filter;
- stabilizing the pH of said sugarcane juice in a non-acidic solution of calcium hydroxide to a preferred pH level within a range of 7.2 to 7.6;
- flocculating said sugarcane juice using a mixture consisting of water and at least one flocculate product;
- evaporating said sugarcane juice via an evaporation apparatus including a series of evaporators, said series of evaporators incrementally increasing a concentration of said sugarcane juice to create a post-evaporation, policosanol-rich concentrated sugarcane juice product; and
- extracting said sugarcane juice concentrate from said evaporation apparatus at a desired degrees Brix value, said sugarcane processing method precluding said juice product from exceeding 90°C throughout said process to minimize evaporation of policosanols therefrom.

The Specification further describes additional steps according to which the resulting juice from Claim 1 is subjected to a third clarification and a process named "inversion", in which the pH is reduced between 4.4 to 4.8 using citric, phosphoric acids or combinations thereof and a temperature between 50.60ºC and an invertase enzyme is added to hydrolyze saccharose (avoiding its crystallization) and producing glucose and fructose, which wan result in liquid and stable sugar cane products. These further steps are recited in dependent Claim 11.

Having clarified the scope and content of Application No. EP3678678A1, and as noted in the arguments describing the common general knowledge, the process for producing sugarcane juice and derived products known as "panela" in Colombia has been in development for more than 30 years. Since the late 80s and early 90s, there are Guidelines and Manuals illustrating how to produce "panela" and other forms of the extracted sugarcane juice (as demonstrated by NPL1). This process has been updated and optimized throughout the years to the point of being a standardized method mostly having the same unitary operations than the one recited in Claim 1 of Application No. EP3678678A1.

For example, document NPL2 available to the public before the priorities claimed by Application No. EP3678678A1 teach in Figures 1 and 2 the diagrams involved in the production of panela and inverted sugar syrup, having the same general steps as recited in Claim 1 (cutting the sugar cane, extracting the sugar cane by a roller mill, removing macro-solids from the resulting juice, juice clarification, evaporation and concentration). When detailing these steps, LP2 explains similar conditions as the ones described un Application No. EP3678678A1. In particular, this document explains that after "cachaza" is removed from the juice, it is concentrated again and the resulting juice is returned to the initial juice (this features is described in Application No. EP3678678A1 as a distinguishing element from the known method).

Similarly, NPL4 is directed to assess the impact of different conditions at the clarification and evaporation steps in the quality of the resulting panela. In addition to disclosing the general steps also recited in Application No. EP3678678A1 (noted above), this document teaches that the step of pH stabilization is critical and that the sugar industry generally uses pHs about 7.0, wherein coagulation is promoted (at lower pHs sugar inversion is more common, wherein saccharose is hydrolyzed to produce glucose and fructose), which is in the pH range between 7.2 and 7.6 recited in Application No. EP3678678A1.

PL2 discloses a process for extracting sugar from sugar cane using an extractant solution comprising water and a surfactant to be added at the steps of extracting the sugarcane juice from milling sugarcane sticks in a roller mill.

Finally, NPL3 discloses the process for inverting sugarcane juice using an enzyme, invertase (particularly, INVERZYME 488, also mentioned in Application No. EP3678678A1), at a pH of 4.5 and a temperature of 50ºC. Diagram 1 generally discloses the process for obtaining sugar cane honey or panela from the sugarcane juice resulting from the concentration process. Thus, when producing sugarcane honey, the sugarcane juice after evaporation and concentration occurred is subjected to an acidic hydrolysis of saccharose (illustrated in Scheme 1). Diagram 2 illustrates that the method for producing sugarcane honey used citric acid to

have a pH of 4.5 at a temperature of 50ºC and an enzyme, such as it is disclosed in the Specification of Application No. EP3678678A1.

Thus, there are several documents, to only mention a few at this stage, that generally disclose a similar process for obtaining a sugar cane juice. One not versed in the technical filed may simply consider that the issue of policosanols extraction was not disclosed before the priority dates claimed by Application No. EP3678678A1. However, as noted in Application No. EP3678678A1, policosanols are naturally occurring compounds found in high concentrations in sugar cane, particularly, in the cortex of the sugar cane. As noted in NPL5, policosanol is the common name given to a mixture of aliphatic primary alcohols (C20 to C36), particularly having docosanol (C22), tetracosanol (C24), hexacosanol (C26), octacosanol (C28) and triacontanol (C30), available in different sources. According to NPL5, sugarcane and rice bran are the most important sources of policosanols.

Furthermore, as explained in NPL6 (Luis Martínez, Evangelina Uribarri, and Abilio Laguna, Characterization and Compatibility Studies between Policosanol, a New Hypocholesterolemic Drug, and Tablet Excipients Using Differential Scanning Calorimetry (DSC), 21 December 1999) the different components of policosanols have melting points between 75.9ºC and 85.7ºC, and experience in a DSC thermogram two endothermic transitions. Additionally, boiling points of the alcohols part of policosanols are above 200ºC. As noted in NPL7 (Barbara Swanson and Joyce Keithley, Policosanol to Manage Dyslipidemia in Older Adults, 2009), policosanol has been shown to melt without decomposition and to remain stable at temperatures up to 185°C, and a promising activity as a natural product for treating dyslipidemia.

Based on the above, it was well-known by the time the priority applications of the instant case were filed that policosanols were naturally occurring in sugarcane and products derived from it. NPL8 (Yonathan Asikin, Takeshi Chinen, Kensaku Takara and Koji Wada, Determination of Long-chain Alcohol and Aldehyde Contents in the Non-Centrifuged Cane Sugar Kokuto, November 2008) aims to determine the presence of long-chain alcohols, particularly, policosanols, in Kokuto, a brown cane sugar traditionally produced in Japan, which is similar to Panela. NPL8 explains the process for preparing kokuto noting that in such a process "sugarcane juice is filtered, concentrated, without molasses removal, and then crystallized," also providing in Fig. 4 a diagram illustrating some of the steps performed for its production. Authors in NPL8 concluded that the kokuto resulting from said process contained several bioactive compounds from sugarcane, including policosanols. In fact, Fig. 1 of NPL8 illustrates the results of a gas chromatography performed in policosanols and aldehyde standards (A) and those found in Kokuto A, demonstrating the presence of docosanol tetracosanol, hexacosanol, octacosanol and triacontanol in kokuto A, which was later confirmed after extracting policosanols from different kokuto (A to G) as illustrated in Table 1 having the policosanol content found in each kokuto type (including C22, C24, C26, C28 and C30), wherein Kokuto A had the highest policosanol content of 86mg/100g.

These findings are also supported by NPL9 (Takafumi Okabe, Takayoshi Toda, Masashi Inafuku, Koji Wada, Hironori Iwasaki, and Hirosuke Oku, Antiatherosclerotic Function of Kokuto, Okinawan Noncentrifugal Cane Sugar, January 2009) wherein the authors determined the policosanol contents in seven samples of kokuto, finding that in the first sample a content of 168.6 mg in 100g of kokuto (as illustrated in Table 1), and 0.77mg per gram of kokuto (as illustrated in Table 4).

Given the lack of evidence in Application No. EP3678678A1 demonstrating that maintaining a temperature throughout the process (or adding a surfactant when extraction occurs) indeed increases the amount of policosanols in the resulting product, it could be concluded that the differences between the claimed invention and LP1 and other documents are arbitrary, and that they do not provide any surprising or unexpected effect (or any effect whatsoever). This is further demonstrated by NPL8 and NPL9 which clearly demonstrate that other sugarcane products resulting from the general traditional process result in high contents of policosanols.

Therefore, it would have been obvious for any skilled artisan in the sugarcane and panela field to perform the well-known steps for producing sugarcane juice (as disclosed in PL1, combined with NPL1-NPL4, NPL8, NPL9, LP2 and the common knowledge in the field) and result in a product with high contents of policosanols. Thus, the claimed method does not comply with inventive

step as established by Art 56 of the European Patent Convention (EPC).

In fact, as evidenced by NPL8 and NPL9, the content of policosanols in sugarcane derived products is an inherent property of these products, since in the process for their production, sugarcane is treated in a traditional well-known manner wherein these compounds are extracted along with other ingredients that ultimately make the panela (or kokuto) and is demonstrated that high contents thereof are found in these products.

## 6. Any further Observations, e.g. Articles 52(2), 53, 57, 76, 83, 84, 123(2) EPC, validity of the priority date

### 6.1. Unallowable amendments (Articles 76 and 123 EPC)

### 6.2. Sufficiency of disclosure (Article 83 EPC)

According to the Guidelines for Examination in the EPO "A detailed description of at least one way of carrying out the invention must be given. Since the application is addressed to the person skilled in the art, it is neither necessary nor desirable that details of well-known ancillary features are given, but the description must disclose any feature essential for carrying out the invention in sufficient detail to render it apparent to the skilled person how to put the invention into practice. A single example may suffice, but where the claims cover a broad field, the application is not usually regarded as satisfying the requirements of Art. 83 unless the description gives a number of examples or describes alternative embodiments or variations extending over the area protected by the claims." (Part F, Chapter III-1). Furthermore, the Guidelines, when explaining an insufficient disclosure, state that one of the instances wherein the Specification is insufficient, is when "the successful performance of the invention is dependent on chance. That is to say, the skilled person, in following the instructions for carrying out the invention, finds either that the alleged results of the invention are unrepeatable or that success in obtaining these results is achieved in a totally unreliable way." (Part F, Chapter III-2).

Finally, the Guidelines also state that "The technical effect achieved by the invention solves the problem which underlies the application. If an invention lacks reproducibility because its desired technical effect as expressed in the claim is not achieved, this results in a lack of sufficient disclosure." (Part F, Chapter III-12).

As noted in the inventive step arguments, the Specification of Application No. EP3678678A1 does not provide a single example of how to perform the complete claimed method. At best, Application No. EP3678678A1 describes each step (including additional steps recited in dependent Claim 11), but it does clearly identify at least an example providing the necessary details so an embodiment of the claimed invention is reproduced by the skilled artisan.

In addition, and more importantly, the Specification explains that the claimed method produces a policosanol-rich sugarcane-based concentrate, but there are no results in the Specification demonstrating the percentage or amount of policosanols in the concentrate obtained by the claimed method.

Therefore, based on the Specification it is not possible for the skilled artisan to follow a well-defined method since no examples are provided, and would not be able to repeat the alleged results. Thus, the claimed invention is not reproducible and there are not results to be repeated by the skilled artisan when carrying out the invention. Therefore, the Application does not meet the provisions of Art. 83 EPC.

### 6.3. Clarity (Article 84 EPC)

### 6.4. Futher observations