Docket No.: 999300-0170

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: ART UNIT: 1781
Petrus J.A. KARSTEN, et al.

SERIAL NO: 16/755,428 EXAMINER: Laura B. Figg

FILED: 04/10/2020

FOR: LAMINATE STRUCTURE FOR BIOCOMPATIBLE BARRIER PACKAGING

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

Sir:

Now comes Petrus Johannes Antonius Karsten who deposes and states that:

1. From 1981 to 1987 I studied chemistry and chemical and process technology at the University of Amsterdam, The Netherlands.

2. I worked for Solvay from 1988 to 2006. In 2006 I started working for Renolit. Since 1988 I have worked since then in research and development in polymer processing, chemistry and technology and management.

3. My field of specialty is polymer processing, chemistry and technology.

4. In 1995, I earned "Certified Polymer Scientist; RPK" from National Dutch Research School (PTN), and Dutch Polymer Institute (DPI), which is linked to the University of Eindhoven, The Netherlands. This is the highest possible title to achieve in polymer science.

5. Since 1995 I have worked in Medical Supplies/Healthcare , developing medical grade plastics for use in hospitals worldwide.

6. From 1997 -2019 I was responsible for all research and development work regarding medical plastics worldwide, first at Solvay and now at Renolit.

7. From 2003 till 2017 I was also responsible for New Medical Business and Development, first at Solvay and later at Renolit.

8. Since 2020 I have been appointed to be the Global Scientist for Renolit Healthcare.

9. I am a co-inventor in the above-captioned application.

10. I have read the Office Action dated March 23, 2021. I understand through the U.S. Attorney that the Examiner has alleged it would have been obvious provide a thermoplastic polymer in U.S. 2001/0008687 A1 ("Kollaja") based at least partly on renewable sources.

11. Based on my academic training and professional experience, in my opinion it is not always easy or even possible to exchange polymers and elastomers with renewably sourced polymers and elastomers while maintaining the desired material properties. This is because in many cases different processes are used to refine the monomers to make the polymers, since not one single process is producing 100% pure monomer, the so called by-products for a process are unique for a particular process. These by products in many cases requires that the catalysts and polymerization ingredients used needs to be modified in order to support an alternative process for producing a similar polymer.

12. I further understand through the U.S. Attorney that the Examiner has alleged the claimed blown film extrusion manufacturing would produce a film having the same materials properties as one produced using cast extrusion as described in Kollaja.

13. Based on my academic training and professional experience, in my opinion a film produced by blown film extrusion according to the claims of U.S. 16/755,428 results in a more flexible and elastic film. The blown film extrusion techniques described therein can also control crystal size as well as how the polymer chains in the resulting material are oriented. Such control is not possible with the approaches discussed in Kollaja. This is because:

a. In a cast process the polymer chains are unevenly oriented in the machine direction of the film in a cast process the polymer flows through a flat die fed by a hole in the middle and then spread out to the full width of the film meaning orientation of the polymer chains is varying over the width of a film. In a blown film process the film due to its circular shape having polymer chains all in the same direction in the film. Since orientation is one of the important parameters defining the way polymeric crystals grow in a process, it can be easily imagined that this can be controlled better with a blown film process then with a cast film process. Crystallization determines many properties of films produced, like flexibility, transparency, strength, ductility, elongation, barrier functions, etc. A better balance is achieved of film physical properties (MD vs TD), like tear strength and elongation, puncture resistance, toughness, especially for linear polymers. The monoaxial drawdown in a cast film process coupled with web neck-in tends to give very splitty cast film from linear polymers.

b. Cast processes uses a chill roll to cool down the film. Blown film uses air (for blown film upwards) or water for blown film downwards. Water, air and steel have all different heat exchange parameters (Q=m.Cp.dT) in which Cp is the heat capacity which for water is the highest with 4.2 J/g.K and 5-10 times higher than for cast steel, and which for air is very low. So with a blown film process you can choose for high cooling speeds and for low cooling speeds which is not possible with a standard cast film process. (m=mass in kg or gram, T in Kelvin, Q heat in Joule). A lower cooling rate give denser and stiffer film and better barrier properties, a higher cooling realizable with water tends to make the film more amoprphous with less haze and more gloss. Because of this, the transpararency (see through) of water quenched blown is much better than cast film which is much better than air cooled blown film. 100% LLDPE for

instance does not have the drawdown instability problems with blownfilm that it has in castfilm (draw down resonance)

c. Blownfilm produces less manufacturing scrap.

14. I further understand through the U.S. Attorney that the Examiner has alleged the claimed components A and B of the laminate recited in present claims of U.S. 16/755,428 would be obvious in view of Kollaja, wherein Polymer A is "homo and co-polymers of ethylene, maleic anhydride grafted polyethylene or polypropylene, and polyamids", and Polymer B is "copolymers of ethylene and vinyl alcohol and polycarbonates."

15. Based on my academic training and professional experience, in my opinion a polymer having such components prepared according to the disclosure of Kollaja would not have an elongation at break > 200% measured according to ISO 527-2.3 or ASTM D882 and a tensile modulus from 75 – 150 MPa measured according to ISO 527-1.2.3 or ASTM D882 at 23 °C and 50% relative humidity. Because:

For packaging especially packaging liquids, impact strength of the film is one of the most important features, a film with a good impact strength when transformed into bags, the bags have to resist impact while transported, brutally handled in some cases, not intentionally dropped in some cases etc. as well as the sealing layer should have a very good seal strength resisting the impact. Films which are flexible and elastic and ductile can absorb energy on impact, the films of Kollaja are not intended to have specific impact resistance or seal strength upon impact. To make a good impact strength of intrinsically brittle polymers like EVOH which can easily stress crack upon impact it is known as indicated in our application that an elastomer can be added, but as indicated in our application this elastomer must be incompatible, which means is has to form a 2nd phase in the continuous phase of the brittle polymer and when it has to be transparent as well the size of this preferably little elastomeric

polymer spheres has to be less than 400nm which is less than the wavelength of visible light. These elastomeric spherical domains in the brittle polymer continuous phase prevents stress cracking upon impact. It's very unlikely a POSA would have considered impact strength as a main parameter when designing conformable film or a POSA would have thought about a conformable film to be used as packaging for liquids.

Kollaja is not mentioning anything a film should be able to absorb energy without deformation on impact, a conformable film is a film which can be deformed around edges and surfaces nicely so it should be not too hard to deform permantly those Kollaja films, the films we propose should be hard to deform permantly (our films aim to be ultimate like a rubber tyre it can deform upon impact but returns after the impact to its original state)

16. I am attaching European pharmacopoeia edition 9 chapter 3 as exhibit A to this Declaration.

17. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

18. Further deponent saith not.

Signature

Date 23 August 2021