Colombian Patent Application No. NC2020/0005132
Declaration

Attorney Reference No.: COLO-20218-0841-0002-3

IN THE COLOMBIAN PATENT OFFICE

IN RE APPLICATION OF:
Jakob Robert BLOK, et al.
FOR: LAMINATE STRUCTURE FOR BARRIER PACKAGING

DECLARATION

Sir/Madam:

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 almost 35 years in research and development in polymer processing, chemistry, and technology.

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, developing medical grade plastics for use in hospitals worldwide.

6. Since 1997 I am responsible for all research and development work regarding medical plastics worldwide, first at Solvay and now at Renolit.

7. Since 2003 I am also responsible for New Medical Business and Development, first at Solvay and now at Renolit.

8. Since 2011 I am also an expert member in group TC 16 of the European Pharmacopoeia for pharmaceutical/medical packaging and disposables.

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

10. I have read the Office Action No. 17177 dated October 24, 2022. I understand through the Colombian Attorney that the Examiner has alleged the indications on barrier properties are expressing the result to be achieved.

11. Based on my academic training and professional experience, in my opinion barrier properties is a feature well known in the art and widely used to differentiate quality of films and laminates for packaging. Barrier properties designates the ability of films and laminates to block the transmission of water vapour, oxygen and other gases as well as volatile organic compounds. The designation "block the transmission" also includes and refers to the degree of blocking, because usual plastics typically have a more or less specific degree of permeability, i.e. fail to achieve complete blocking. Therefore, barrier properties are typically measured as transmission rate for a specific substance.

12. The actually measured transmission rate for a specific plastic film or laminate depends on many circumstances including the thickness of the film or laminate, the temperature and the substance under consideration. However, there are also generally applicable rules, above all the intrinsic ability to block transmission of a specific plastic and that thicker films are less permeable.

13. Specifically, it is well known in the art that ethylene vinylalcohol, polyvinylalcohol and polyamide show barrier properties for, i.e. have a very low transmission of, oxygen and other gases as well as volatile organic compounds. In contrast, polyolefins like polyethylene and polypropylene are known to provide no barrier, i.e. they show a high transmission rate for oxygen and other gases as well as volatile organic compounds.

14. Analogously, the measured value for water vapour transmission rate depends on many factors, but some plastics are known to generally have high transmission and other plastic are known to have low transmission. For example, polyolefins are accepted to have barrier properties against water vapour transmission while ethylene vinylalcohol shows a high transmission of water vapour.

15. Barrier properties, i.e. the transmission rate of water vapour and/or oxygen measured for a specified film sample from the plastic, are also often listed on technical data sheets for plastics.

16. Thus, based on my academic training and professional experience, in my opinion the expressions in claim 1 criticized as "result to be achieved" are functional features of the laminate structure that one of ordinary skill in the art can easily achieve following the remaining definitions of claim 1, i.e. using the listed polymers in the specified alternating layer stack with layers having the specified thickness and admixing an elastomer C to polymer A and/or an elastomer D to polymer B as defined.

17. Further, regarding barrier properties, the transmission rate typically is inversely proportional to the thickness of the material (thickness goes up permeation rate

goes down). However, this may not solely apply for very thin layers where structural changes (orientation (polymer chains forces to stretch because of reduced free volume in very thin layers), crystallization (due to reduced thermodynamic free volume polymer chains forced to crystallize)) may occur. Crystallization and orientation will increase the barrier properties of a given material (denser), a bit more than expected for the thickness given. On the other hand, especially for nanolayers the chance of creating voids and cracks in the continues layer increases with decreasing thickness. Voids and cracks will decrease barrier properties. To prevent or at least reduce the forming of voids and cracks a thermoplastic elastomer, sometimes also called rubber (not vulcanized) can be added. But the thermoplastic elastomer must be incompatible with the barrier polymer matrix as mentioned in the application for my invention. In this way when blended the elastomer forms non touching nanospheres in the continuous layer of the barrier polymer (at least if not added so much that phase inversion occurs. i.e., the elastomer becomes the continuous layer). The nanospheres prevent propagation of cracking therefore increase barrier properties for a given thickness. Besides, those soft and flexible nanospheres of thermoplastic elastomer increase the flexibility of the barrier polymer layer and it may also increase the barrier properties because of a permeant need to go around the spheres therefore the pathway of the permeant may be lengthened. Because of less cracking and pinhole forming by adding a certain percentage of the carefully selected thermoplastic elastomers in a thin layer (nm region), toughness of the layer will increase severely and since the nanospheres will be far less than 400 nm in diameter visible light will not be blocked and so transparency not affected. One step further is to make multiple thin layers typically multilayer materials obeying Fick's law in which the transmission rate of a permeant can be mathematically added by means of the "Parallel Resistance Equation" 1/TRtotal=1/TRa + 1/TRb + 1/TRc + …etc. (TR is thickness dependent). For multiple thin layers toughness, impact resistance and flexibility of the total film will be better for a same material than one layer of the same thickness overall. (A commonly known example is multilayer plywood used in construction, which is stronger, tougher, and more flexible than a single wood layer, in plastics this effect is no different physically. When a barrier film is made from many thin barrier layers the crack resistance of the total film increases because if cracks occur (in z-direction) they will be statistically seen not exactly on top of each other (in x-y direction). So, in conclusion structure, interactants, basic polymer characteristics, polymer additives like thermoplastic elastomers and additives (antioxidants, antiacids), thickness and multiple layers all influence packaging and its barrier performance. Especially a significant benefit from adding thermoplastic elastomers (incompatible) to the barrier materials in multiple thin layers will create a significant increase in desired properties.

18. Further deponent saith not.

Signature

30 January 2023

Date