

Bogotá D.C., October 1, 2019.
PI-04129-19 / 6917.

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Reference: **Patent application**
Client: **GLENMARK PHARMACEUTICALS LIMITED**
Your Ref: **jjm/egc**
Title: **Composiciones farmaceuticas de montelukast y levocetirizina.**
File No.: **NC2018/0007016**
Our Ref.: **WM-CO-3981-PAT-0001**
Subject: **Opposition filed by Laboratorio Franco Colombiano LaFranco S.A.S.**

Dear Sirs,

Our Patent Office has recently issued a new Office Action No. 9050 related to the above referenced Patent Application. The examiner raised the following remarks and objections as follows:

1. Opposition

According to the present Office Action, the Examiner did not accept the opposition filed by Laboratorio Franco Colombiano S.A.S. LAFRANCOL S.A.S.

2. Patentability analysis.

After the search for prior art, a document was found:

D1 RU 2013107724 “The pharmaceutical compositions of montelukast and levocetirizine” published on August 27, 2014.

Based on the above document, the Examiner concluded that claims 1 to 8 are not new.

The arguments of the Examiner are as follows:

Novelty (Art 16 D 486)

Claim 1 consists in: “An oral administration pharmaceutical composition comprising a) montelukast or salts thereof in an amount around 10.4 mg; b) levocetirizina or salts thereof in an amount of 5.0 mg, lactose monohydrate, microcrystalline cellulose, anhydrous dibasic calcium phosphate, sodium crosscarmellose and hydroxypropyl cellulose. (File No. NC2018/0007016 of July 4, 2018).

Comparison of the essential technical characteristics with those of the State of the Art:

Essential Characteristics	D1
Oral administration pharmaceutical composition comprising:	Oral administration pharmaceutical composition comprising: (Claim 1)
Montelukast 10.4 mg	Montelukast 10.4 mg (Claim 1)
Levocetirizine 5.0 mg	Levocetirizine 5.0 mg (Claim 1)
Lactose monohydrate	Lactose monohydrate (Claim 1)
Microcrystalline cellulose	Microcrystalline cellulose (Claim 1)
Anhydrous dibasic calcium phosphate	Anhydrous dibasic calcium phosphate (Claim 1)
Sodium Crosscarmellose	Sodium Crosscarmellose (Claim 1)
Cellulose hydroxypropyl	Cellulose hydroxypropyl (Claim 1)

According to the above comparative table, the essential characteristics of the montelukast and levocetirizine oral administration pharmaceutical composition of claim 1 were previously disclosed in document D1, therefore, the claimed subject matter is not new.

Additionally, document D1 mentions that the compositions comprise sodium montelukast, levocetirizine dihydrochloride, microcrystalline cellulose and dibasic calcium phosphate in a 1:1 proportion; the composition is in the form of a fixed dose; the pharmaceutical form is a pill having an enteric layer and a process for preparing the composition comprising the following

steps: a) mixing sodium montelukast, lactose monohydrate, microcrystalline cellulose, anhydrous dibasic calcium phosphate and sodium crosscarmellose; b) solving hydroxypropyl cellulose in a solvent to form a binding solution; c) granulating the mixture of step a) using the binding solution of step b); d) mixing the granules of step c) with levocetirizine dihydrochloride, sodium crosscarmellose and microcrystalline cellulose; e) lubricating the mixture of step d) with magnesium stearate; f) compressing the mixture of step e); g) optionally coating the pills of step f) or the lubricated mixture of step e) and filling them into the capsules (claims 2 to 8).

Claims 2 to 8 do not comply with novelty requirement.

Our suggestions:

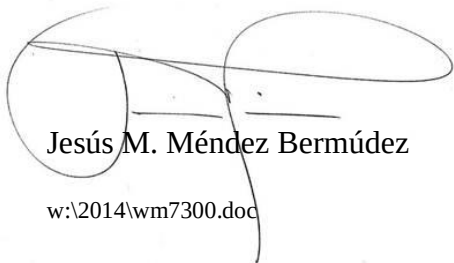
Strong arguments must be drafted in order to reverse this novelty rejection. Your comments and instructions will be greatly appreciated in order to draft a suitable response to this Office Action.

A response must be filed on or prior to **November 26, 2019.**

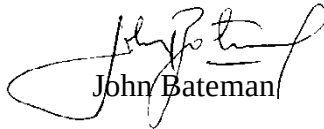
If you require more time to prepare the instructions, please inform us to request an extension for 30 working days without cost for you or your client.

We will be awaiting your comments and instructions in this connection.

Sincerely yours,



Jesús M. Méndez Bermúdez
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John Bateman



David J. Méndez